


**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

<p>PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC and ENDO PAR INNOVATION COMPANY, LLC,</p> <p style="text-align: center;">Plaintiffs,</p> <p style="text-align: center;">v.</p> <p>EAGLE PHARMACEUTICALS INC.,</p> <p style="text-align: center;">Defendant.</p>	<p style="text-align: center;">C.A. No. 18-cv-823-CFC-JLH</p> <p style="text-align: center;"></p>
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AMENDED JOINT [PROPOSED] PRETRIAL ORDER

This matter comes before the Court at a final pretrial conference held pursuant to Rule 16 of the Federal Rules of Civil Procedure. Plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC (collectively “Plaintiffs” or “Par”) and Defendant Eagle Pharmaceuticals Inc. (“Defendant” or “Eagle”), by their undersigned counsel, collectively submit this proposed Joint Pretrial Order pursuant to D. Del. L.R. 16.3. The parties attempted in good faith to reach consensus on the following issues. To the extent the parties had differing positions, each parties’ respective proposal is explained for the Court’s consideration. The Pretrial Conference and a bench trial that were previously scheduled for May 7, 2020 and May 18, 2020 have been

postponed. A Telephone Conference was held on May 18, 2020 and the trial was postponed due to the pandemic after a Pretrial Order was submitted, D.I. 187. Trial in this case was rescheduled and this case is to be tried along with 18-cv-2032-CFC (the “Amneal Action”). The Pretrial Conference is scheduled for January 5, 2021 and trial is scheduled for January 11, 2021. The Court has determined that this trial will be conducted via Zoom[®]. As a result, the parties have worked together with the Defendant in 18-cv-2032-CFC to submit a separate proposed joint order governing additional aspects of the trial. In addition to new material in this introductory paragraph and paragraph 38 below, amended versions of Exhibits 1-5, 7, and 8 are submitted herewith.

I. NATURE OF THE CASE AND PLEADINGS

A. Nature of the Action

1. This is a Hatch-Waxman patent infringement action in which Par asserts that Eagle has infringed and will infringe U.S. Patent Nos. 9,687,526 (“the ’526 patent”), 9,744,209 (“the ’209 patent”), and 9,750,785 (“the ’785 patent”) (collectively, the “Asserted Patents”). These actions arise under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.* The accused product is described in Abbreviated New Drug Application (“ANDA”) No. 211538, filed under 21 U.S.C. § 355(j) seeking approval from the United States Food and Drug Administration (“FDA”) to engage in the commercial manufacture, use, and sale of a proposed

generic Vasopressin Injection USP, 20 units/1 mL (20 units/mL) product. Par asserts that Eagle infringes claim 13 of the '526 patent, claims 1, 3, 4, 5, and 7 of the '209 patent, and claims 1, 4, 5, and 8 of the '785 patent (the "Asserted Claims"). Eagle asserts that it does not infringe any of the Asserted Claims and that the Asserted Claims are invalid and unenforceable.

2. The operative pleadings are Par's Complaint (D.I. 1), Eagle's First Amended Answer to Complaint and Counterclaims (D.I. 136), and Par's Answer to Eagle's Amended Counterclaims (D.I. 167).¹

3. The Court issued an Order on claim construction on July 1, 2019 (D.I. 71).

II. JURISDICTION

4. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), 21 U.S.C. § 355(j)(5)(C), and 28 U.S.C. §§ 2201 and 2202. Venue is proper in this district pursuant to 28 U.S.C. §§

¹ Par is no longer asserting U.S. Patent Nos. 9,375,478 ("the '478 patent"), 9,744,239 ("the '239 patent"), and 9,937,223 ("the '223 patent"), and the parties' respective claims and counterclaims as to those patents were dismissed by stipulation of the parties (D.I. 164). Eagle contends it is entitled to costs and attorney fees under 35 U.S.C. § 285 based on Par's assertion of the '239 patent, '223 patent, and '478 patent in this action and that the Asserted Patents are unenforceable due to alleged inequitable conduct, in part based on actions during prosecution of the '239 patent.

1391(b) and 1400(b), and 21 U.S.C. § 355(j)(5)(C)(i)(II). Jurisdiction and venue are not disputed.

III. STATEMENT OF ADMITTED FACTS

5. The parties stipulate to the facts listed in the attached **Exhibit 1**.

These proposed stipulated facts require no proof at trial and will become part of the evidentiary record in this case.

IV. STATEMENTS OF CONTESTED ISSUES OF FACT

6. Plaintiffs' statement of contested issues of fact is attached as **Exhibit 2**.

7. Defendant's statement of contested issues of fact is attached as **Exhibit 3**.

V. STATEMENTS OF CONTESTED ISSUES OF LAW

8. Plaintiffs' statement of contested issues of law is attached as **Exhibit 4**.

9. Defendant's statement of contested issues of law is attached as **Exhibit 5**.

VI. EXHIBITS

A. Exhibit Lists

10. The parties' joint list of exhibits is attached as **Exhibit 6**.

11. Plaintiffs' list of exhibits and Defendant's objections thereto is attached as **Exhibit 7**.

12. Defendant's list of exhibits and Plaintiffs' objections thereto is attached as **Exhibit 8**.

13. Subject to the remaining provisions of this Order, no party may add to its exhibit list or use at trial an exhibit not present on its list absent good cause. Each party reserves the right to offer exhibits from any other party's trial exhibit list, even if not separately listed on its own exhibit list. The demonstrative exhibits the parties intend to use at trial do not need to be included on their respective exhibit lists. The parties also agree that any description of a document on an exhibit list is provided for convenience only and shall not be used as an admission or otherwise as evidence regarding the document.

14. Exhibits to be used solely for impeachment need not be included on the lists of trial exhibits or disclosed in advance of being used at trial. Such exhibits used solely for impeachment and not included on an exhibit list may not be admitted into evidence.

15. Statements from any request for admission responses, interrogatory responses, or pleadings may be read at trial and need not be included on the exhibit lists.

B. Demonstratives and Summary Exhibits

16. Notwithstanding any contrary provisions in this Order, the parties will disclose and exchange copies of demonstrative and summary exhibits in accordance with the following procedure.

17. Plaintiff's demonstratives will be identified with PDX numbers.

18. Defendants' demonstratives will be identified with DDX numbers.

19. The parties shall exchange complete color representations of all demonstrative exhibits, excluding those for opening and closing statements, no later than 7:00 p.m. the night before they will be used in Court and any objections thereto will be lodged by 9:00 p.m. that same night.² The parties shall meet and confer at 10:00 p.m. that night to resolve the objections.

20. By no later than 5:00 p.m. on the calendar day before the opening statements, the Parties shall exchange color copies of demonstrative exhibits that they intend to use in their respective opening statements. By no later than 7:00 p.m. that same day, any objections to the demonstrative exhibits shall be lodged. By no later than 8:00 p.m. that same day, the parties shall meet and confer to resolve any objections, which if necessary will be raised with the Court the following morning.

² All times set forth herein refer to Eastern Daylight Time (EDT).

21. The party seeking to use a demonstrative will provide a color representation of the demonstrative to the other side in PDF form. However, for video or animations, the party seeking to use the demonstrative will provide it to the other side via DVD, CD, flash drive, email, or secure FTP or Box website. For irregularly sized physical exhibits, the party seeking to use the demonstrative will provide a color representation as a PDF or 8.5 x 11 copies of the exhibits, in addition to making them available for inspection.

22. The provisions in this section do not apply to demonstratives created during testimony or argument at trial or to demonstratives to be used for cross examination, neither of which need to be provided to the other side in advance of their use. In addition, ballooning, blow-ups, excerpting, or highlighting of exhibits or parts of exhibits or testimony are not required to be provided to the other side in advance of their use.

23. If good faith efforts to resolve objections to demonstrative or physical exhibits fail, the objecting party shall raise its objections with the Court prior to their anticipated use.

24. Any exhibit identified on a party's exhibit list and not objected to is deemed to be authentic and admissible and may be entered into evidence by the party, except that nothing herein shall be construed as a stipulation or admission that the document is entitled to any weight in deciding the merits of this case.

25. The parties stipulate to the authenticity of the documents listed in the attached exhibit lists unless such objections are specifically and expressly preserved therein. The parties further agree that they will not dispute the authenticity of any document that was produced during discovery, which on its face appears to have been authored by an employee, officer or agent of the producing party in the ordinary course of business, and that such documents shall be deemed prima facie authentic, subject to the right of the party against whom such a document is offered to adduce evidence to the contrary or to require the offering party to provide authenticating evidence if the opposing party has a reasonable basis to believe the document is not authentic and subject to any contrary determination or ruling by the Court.

26. Complete legible copies of documents may be offered and received in evidence to the same extent as an original unless a genuine question is raised as to the authenticity of the original, or in the circumstances it would be unfair to admit the copy in lieu of the original. Legible copies of United States patents may be offered and received in evidence in lieu of certified copies thereof, subject to all other objections that might be made to the admissibility of certified copies.

VII. WITNESSES & EXHIBIT DISCLOSURE PROCEDURE

A. Live Witnesses & Exhibits

27. Plaintiffs' list of the names of the fact and expert witnesses that they intend to call at trial is attached as **Exhibit 9**.

28. Defendant's list of the names of the fact and expert witnesses that it intends to call at trial is attached as **Exhibit 10**.

29. Any witness not listed in the exhibits referenced above will be precluded from testifying absent good cause shown, except that each party reserves the right to call such rebuttal witnesses (who are not presently identifiable) as may be necessary. Defendant shall identify any such un-listed rebuttal witnesses that they intend to call no later than the close of Plaintiffs' case-in-chief. Plaintiffs shall identify any such un-listed rebuttal witnesses that they intend to call no later than the close of Defendant's rebuttal. Subject to the notice requirements adopted by the Court, the listing of a witness on a party's pre-trial witness list does not require that party to call that witness to testify, and does not necessarily mean that the listing party has the power to compel the live testimony of that witness.

30. For those depositions that have been videotaped, to the extent admissible, a party may introduce the deposition excerpt by videotape instead of, or in addition to, by transcript. If a party opts to introduce deposition testimony by

videotape, any counter-designations of that same witness's deposition testimony must also be submitted by videotape.

31. When deposition designation excerpts are introduced, all admissible deposition counter-designation excerpts, whether offered by videotape or by transcript, will be introduced simultaneously in the sequence in which the testimony was originally given. To the extent such designations are read or played in open court, each party will be charged for the time taken to read or play its designations. If the parties cannot agree on an appropriate time apportionment for the designations, each party will be charged for the proportion of lines of testimony for its designations to the total number of lines of testimony read or played. The parties agree to edit out deposition objections and long pauses between the end of an answer and the start of the next question from the clips of the deposition designations to be played to the Court, and further agree to meet and confer regarding any designated colloquy, i.e., between counsel.

32. Each side will provide to the other side the name of any witness that it intends to call to testify, whether live or by deposition testimony, the exhibits to be introduced through each such witness, and the order of presentation of those witnesses, by no later than 7:00 p.m. two days before the day the witness is expected to testify. Thereafter, each side shall update its expected witnesses at the end of each trial day by 7:00 p.m. If later events cause the need to remove a

witness from a party's witness list, the parties agree to notify the other side as soon as possible. Objections to the identified exhibits to be introduced on direct examination shall be provided by 7:00 p.m. the following evening. The parties shall meet-and-confer by 10:00 p.m. the same day regarding any objections to the identified exhibits. Thus, for example, the parties will provide notice of what witness they intend to call live and the exhibits they will use on direct examination on a Monday by the previous Saturday at 7:00 p.m. and objections thereto shall be provided by 7:00 p.m. Sunday, with a meet-and-confer to occur as necessary by 10:00 p.m. Sunday. Any disputes or objections that cannot be resolved shall be raised with the Court before calling such witnesses or using any such exhibits during examination of the witness.

33. The parties agree that this provision does not require the disclosure of exhibits to be used for cross examination or redirect examination.

34. Prior to the start of the direct or cross examination of any witness, the parties agree to provide the other with two copies of witness binders that contain all of the exhibits expected to be used on direct or cross examination of that witness. The parties will also make available to the Court, the court reporter, the clerk, and the witness binders of exhibits to be used during direct or cross examination of the witness

35. For a witness who is to testify out of order or has limitations or requirements with regard to timing or availability, the sponsoring party must, if possible, raise these issues no later than two calendar days prior to the day said witness is to testify in order for the Court to have sufficient time to resolve any issues, as necessary. The parties agree to be reasonable and cooperate in permitting witnesses to testify out of order due to scheduling issues outside of the witness' or parties' controls.

B. Deposition Designations

36. Plaintiffs' list of deposition designations, Defendant's objections to Plaintiffs' designations, Defendant's counter-designations, and Plaintiffs' objections to such counter-designations are attached as **Exhibit 11**.

37. Defendant's list of deposition designations, Plaintiffs' objections to Defendant's designations, Plaintiffs' counter-designations, and Defendant's objections to such counter-designations are attached as **Exhibit 12**.

38. **[Par Proposal]**: Now that this case has been consolidated for trial with the Amneal Action, all deposition designations for a given witness (where designations have been made in both actions) shall be combined and only played once. **[Eagle's Proposal]**: Now that this case has been consolidated for trial with the Amneal Action, all deposition designations for a given witness (where designations have been made in both actions) shall be only played once. However,

Par may not rely on deposition testimony elicited in the Amneal Action for its case against Eagle. To the extent that testimony elicited in the Amneal Action will be played at the consolidated trial, the parties must make clear to the Court that such testimony was taken in the Amneal Action and cannot be used against Eagle in the Eagle Action.

39. Absent good cause shown, no deposition testimony not previously designated pursuant to this Order may be later added for these witnesses.

40. With respect to those witnesses who will be called to testify at trial (designated in the Pretrial Order as “will call”), no deposition designations or counter-designations are required. A party shall promptly provide notice if for any reason it does not intend to call live a witness who is so identified on the list of trial witnesses. To the extent a party gives notice that a fact witness identified as a live witness on the list of trial witnesses is not going to be called live, the opposing party may designate specific pages and lines of transcript that it intends to read or play in lieu of the witness’s appearance at least 72 hours prior to introducing the deposition testimony. **[Eagle’s proposal:** Further, to the extent a party intends to call a live witness at trial who has not been previously deposed in this action, said party will provide notice of its intention to do so at least 30 days prior to the beginning of trial and offer the witness for deposition at least two weeks prior to the beginning of trial, unless otherwise agreed by the parties.]

41. Each party reserves the right to offer testimony designated by any other party (whether as a designation or counter-designation), even if not separately listed on its own deposition designation list.

42. The parties may offer some or all of the deposition testimony set forth herein at trial. A party's decision not to introduce some or all of the testimony of a witness designated by that party herein shall not be commented upon by the other party at trial. However, for those witnesses to be presented via deposition testimony, the parties agree that the proffering party will provide the initial deposition designations (by page and line number) that are actually intended to be played or read at trial, or a disclosure that all pages and lines previously designated will be played by 6:00 p.m. three days prior to the day that testimony will be offered. By 6:00 p.m. the following day (two days prior to the day that the testimony will be offered), the other party will provide the specific pages and lines it counter-designates and any objections. By 8:00 p.m. the same day, the proffering party will provide objections. The parties shall meet-and-confer by 10:00 p.m. the same day regarding any objections to the deposition designations. If the objections to the disputed testimony cannot be resolved by the parties, the objections will be presented to the Court as appropriate before trial resumes on the day the testimony is expected to be introduced. By 6:00 p.m. the day before the witness will be offered by videotaped deposition, the offering party

will provide to all parties the transcript clip and a copy of the video containing the designations from all parties for that witness.

43. For rebuttal deposition testimony where compliance with the three-day deadline in the preceding paragraph is impracticable, such deadline shall not apply, and the parties will act in good faith to designate rebuttal testimony in time to allow for counter-designations, and any objections, and the parties will meet and confer to resolve the objections and to give the introducing party time to prepare any necessary video/DVD of the testimony. **[Eagle's proposal:** Further, if any non-rebuttal witness that a party intended to call live unexpectedly becomes unavailable through no fault of that party such that compliance with the three-day deadline in the preceding paragraph becomes impracticable, the parties agree to cooperate in good faith to allow for deposition designations, counter-designations, and any objections thereto for such witness to be made, and the parties will meet and confer to resolve the objections and to give the introducing party time to prepare any necessary video/DVD of the testimony.]

44. Copies of exhibits referred to during the introduction of deposition testimony will be offered into the trial evidence record to the extent admissible. Where a video recording of a deposition is available, the offering party shall play portions of the video containing the designated testimony at trial. Where a video recording of the deposition is not available, the offering party shall read the

designated testimony into the record at trial. Whether introduced via video recording or read into the record, deposition testimony shall count toward the offering party's total allotted time in court. The parties shall provide the court with a stipulated record of the total time allocated to each party's designations.

45. Any deposition testimony may be used at trial for the purpose of impeachment, regardless of whether a party specifically identified that testimony on its list of deposition designations, if the testimony is otherwise competent for such purpose.

VIII. BRIEF STATEMENT OF WHAT PLAINTIFFS INTEND TO PROVE

46. A brief statement of what Plaintiffs intend to prove in support of Plaintiffs' claims is attached as **Exhibit 13**.

IX. BRIEF STATEMENT OF WHAT DEFENDANT INTENDS TO PROVE

47. A brief statement of what Defendant intends to prove as defenses is attached as **Exhibit 14**.

X. AMENDMENTS TO PLEADINGS

48. The parties do not seek to amend the pleadings.

XI. CERTIFICATION REGARDING SETTLEMENT

49. The parties certify that they have engaged in a good-faith effort to explore the resolution of the controversy by settlement. The parties have been unable to reach agreement.

XII. OTHER MATTERS

50. The Court has entered a Stipulated Protective Order to safeguard the confidentiality of certain of the parties' business and technical information, as well as that of third parties. All outside counsel shall handle such protected information in accordance with the terms of the Protective Order and shall not disclose such Confidential Information to persons not authorized to view such information under the terms of the Protective Order. Nonetheless, the presentation of evidence at trial shall take place in open court, unless a party specifically requests, and the Court agrees, that the Court be closed to the public during presentation of certain portions of the evidence.

51. The parties have agreed that each party may have up to three corporate representatives (total) attend the entire trial, including any closed portions. The corporate representatives need not have been listed in the Protective Order. However, if a corporate representative is not listed in the Protective Order, that representative may not have access to the other party's confidential information except for that presented at trial. The corporate representatives must agree to maintain in confidence the confidential information of the opposing party and all third parties that is presented during any closed portion of the trial, and to use such information only in connection with this litigation and not for any other purpose, including competitive decision making, communications with FDA,

and/or patent applications or prosecution relating to any products. Fact witnesses other than corporate representatives shall not be present in the courtroom during the presentation of evidence or arguments until they are called to testify. Expert witnesses may be present in the courtroom at any time during trial.

52. Subject to the approval of the Court, the parties propose the following order for trial:

Plaintiffs then Defendant shall present their opening statements. Plaintiffs will then present their case-in-chief on infringement. Defendant will present its rebuttal case on infringement, and case-in-chief on invalidity and unenforceability. Plaintiffs will then present their rebuttal case on validity and enforceability.

53. Plaintiffs' motions *in limine*, along with Defendant's oppositions, and Plaintiffs' replies, are attached as **Exhibit 15**.

54. Defendant's motions *in limine*, along with Plaintiffs' oppositions, and Defendant's replies, are attached as **Exhibit 16**.

XIII. ORDER CONTROLS

55. This order shall control the subsequent course of the action, unless modified by the Court to prevent manifest injustice.

Respectfully submitted,

<p>DATED: January 4, 2021</p> <p>OF COUNSEL:</p> <p>Martin J. Black Sharon K. Gagliardi Brian M. Goldberg DECHERT LLP Cira Centre 2929 Arch Street Philadelphia, PA 19104 Tel: (215) 994-4000 martin.black@dechert.com sharon.gagliardi@dechert.com brian.goldberg@dechert.com</p> <p>Robert D. Rhoad DECHERT LLP 502 Carnegie Center, Suite 104 Princeton, NJ 08540-7814 Tel: (609) 955-3200 robert.rhoad@dechert.com</p> <p>Jonathan D. J. Loeb, Ph.D DECHERT LLP 2400 W. El Camino Real, Suite 700 Mountain View, CA 94040-1499 Tel: (650) 813-4995 jonathan.loeb@dechert.com</p> <p>Blake B. Greene DECHERT LLP 300 W. 6th Street, Suite 2010 Austin, TX 78701 Tel: (512) 394-3000 blake.greene@dechert.com</p>	<p>Respectfully submitted,</p> <p>FARNAN LLP</p> <p>By: <u>/s/ Michael J. Farnan</u> Brian E. Farnan (Bar No. 4089) Michael J. Farnan (Bar No. 5165) 919 North Market St. 12th Floor Wilmington, DE 19801 Tel: 302-777-0300 Fax: 320-777-0301 bfarnan@farnanlaw.com mfarnan@farnanlaw.com</p> <p><i>Attorneys for Plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC</i></p>
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SO ORDERED this ____ day of _____, 2021

UNITED STATES DISTRICT JUDGE

EXHIBIT 1

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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

<p>PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC and ENDO PAR INNOVATION COMPANY, LLC,</p> <p>Plaintiffs,</p> <p>v.</p> <p>EAGLE PHARMACEUTICALS INC.,</p> <p>Defendant.</p>	<p>C.A. No. 18-cv-823-CFC</p> <p>[REDACTED]</p>
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STATEMENT OF THE FACTS
WHICH ARE ADMITTED AND REQUIRE NO PROOF

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I. THE PARTIES

1. Plaintiff Par Pharmaceutical, Inc. (“Par Pharmaceutical”) is a corporation organized and existing under the laws of the State of New York, having a principal place of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977. Par Pharmaceutical develops, manufactures, and markets pharmaceutical products in the United States.

2. Plaintiff Par Sterile Products, LLC (“Par Sterile Products”) is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977. Par Sterile Products develops, manufactures, and markets injectable pharmaceutical products, and provides manufacturing services to the biopharmaceutical and pharmaceutical industry.

3. Plaintiff Endo Par Innovation Company (“EPIC”) is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977.

4. Plaintiffs Par Pharmaceutical, Par Sterile Products, and EPIC are referred to collectively as “Par.”

5. Defendant Eagle (“Eagle”) is a corporation organized under the laws of the State of Delaware having a principal place of business at 50 Tice Road, Suite 315, Woodcliff, New Jersey, 07677. Eagle develops and markets

pharmaceutical products, including injectable pharmaceutical products, in the United States.

II. PAR'S VASOSTRICT® PRODUCTS

6. Vasopressin is a peptide drug that causes contraction of vascular and other smooth muscle cells.

A. Original VASOSTRICT®

7. On September 25, 2012, JHP Pharmaceuticals, LLC submitted NDA No. 204485 under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, seeking approval from the United States Food and Drug Administration (“FDA”) for a vasopressin injection product to increase blood pressure in adults with vasodilatory shock.

8. On February 20, 2014, Par Pharmaceutical Companies, Inc. acquired JHP Pharmaceuticals, LLC. On February 26, 2014, JHP Pharmaceuticals, LLC changed its name to Par Sterile Products, LLC.

9. On April 17, 2014, FDA approved NDA No. 204485. The trade name for the approved vasopressin product was VASOSTRICT®.

10. The VASOSTRICT product as approved in April 2014 had a shelf life of 12 months at room temperature storage.

11. Par filed a supplement to its NDA (204485/S-001) seeking approval for storage between 2 °C and 8 °C and change in shelf life expiration—24 months

at refrigerated storage. FDA approved that supplement (NDA 204485/S-001) on September 18, 2014.

12. VASOSTRICT was first sold and offered for sale in November 2014, with the approved September 2014 label. That label discloses that the 1 mL solution of Original VASOSTRICT “contains vasopressin 20 units/mL, chlorobutanol, NF 0.5% as a preservative, and Water for Injection, USP adjusted with acetic acid to pH 3.4 – 3.6.”

13. Par subsequently filed a second supplement to its NDA (204485/S-002) seeking approval for room temperature storage for up to 12 months following removal from storage at refrigerated conditions. FDA approved that supplement (NDA 204485/S-002) on May 7, 2015.

14. The parties refer to the formulation as described in NDA 204485, NDA 204485/S-001, and NDA 204485/S-002 and approved on April 17, 2014, September 18, 2014, and May 7, 2015 as “Original VASOSTRICT.”

15. Original VASOSTRICT was indicated to increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy or sepsis) who remain hypotensive despite fluids and catecholamines.

16. Par first sold Original VASOSTRICT in November 2014.

B. Reformulated VASOSTRICT®

17. Subsequently, Par Sterile Products filed a further supplement to its NDA (204485/S-003) seeking approval for a new 1 mL formulation of VASOSTRICT. Changes to the formulation of VASOSTRICT in this supplement included addition of a sodium acetate buffer and change in pH—from 3.4 to 3.6 in Original VASOSTRICT to 3.8 in Reformulated VASOSTRICT. On March 18, 2016, FDA approved NDA 204485/S-003.

18. Thereafter, Par Sterile Products filed an additional supplement to its NDA (204485/S-004) seeking approval for a 10 mL multi-dose formulation of VASOSTRICT with the same concentration of vasopressin as the 1 mL formulation (i.e., 20 units of vasopressin/mL). On December 17, 2016, FDA approved NDA 204485/S-004.

19. The parties refer to the current formulation of VASOSTRICT—approved on March 18, 2016 and December 17, 2016—as “Reformulated VASOSTRICT.”

20. The approved label for Reformulated VASOSTRICT (DTX-224 at PAR-VASO_0014544-545) discloses that it “is a sterile, aqueous solution of synthetic arginine vasopressin for intravenous administration. The 1 mL solution contains vasopressin 20 units/mL, Water for Injection, USP and, sodium acetate buffer adjusted to a pH of 3.8.”

21. Reformulated VASOSTRICT is indicated to increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy or sepsis) who remain hypotensive despite fluids and catecholamines.

22. Par first sold Reformulated VASOSTRICT in September 2016.

23. After approval of Reformulated VASOSTRICT, Par Sterile Products discontinued the sale of Original VASOSTRICT.

24. Par Sterile Products is the holder of NDA No. 204485 for VASOSTRICT, including all supplements thereto.

III. PATENT CLAIMS ASSERTED BY PAR

25. On June 27, 2017, the United States Patent and Trademark Office (“PTO”) issued U.S. Patent No. 9,687,526 (“the ’526 patent”), entitled “Vasopressin Formulations for Use in Treatment of Hypotension,” to Par Pharmaceutical as assignee. Matthew Kenney, Vinayagam Kannan, Sunil Vandse, and Suketu Sanghvi are named as inventors.

26. The ’526 patent was filed on October 10, 2016, as U.S. Application No. 15/289,640 (the “’640 Application”). The ’640 Application is a continuation-in-part of Application No. 14/717,877 (“the ’877 Application”) (issued as U.S. Patent No. 9,744,239 (“the ’239 patent”)).

27. Eagle alleges that the effective filing date for the '526 patent is October 10, 2016. For purposes of this case only, Par accepts that date as the effective filing date.

28. On August 29, 2017, the PTO issued U.S. Patent No. 9,744,209 ("the '209 patent"), entitled "Vasopressin Formulations for Use in Treatment of Hypotension," to Par Pharmaceutical as assignee. Matthew Kenney, Vinayagam Kannan, Sunil Vandse, and Suketu Sanghvi are named as inventors.

29. The '209 patent was filed on February 7, 2017, as U.S. Application No. 15/426,693 (the "'693 Application"). The '693 Application is a continuation-in-part of the '640 Application, which is a continuation-in-part of the '877 Application.

30. Eagle alleges that the effective filing date for the '209 patent is February 7, 2017. For purposes of this case only, Par accepts that date as the effective filing date.

31. On September 5, 2017, the PTO issued U.S. Patent No. 9,750,785 ("the '785 patent"), entitled "Vasopressin Formulations for Use in Treatment of Hypotension," to Par Pharmaceutical as assignee. Matthew Kenney, Vinayagam Kannan, Sunil Vandse, and Suketu Sanghvi are named as inventors.

32. The '785 patent was also filed on February 7, 2017, as U.S. Application No. 15/426,703 (the "'703 Application"). The '703 Application is a

continuation-in-part of the '640 Application, which is a continuation-in-part of the '877 Application.

33. Eagle alleges that the effective filing date for the '785 patent is February 7, 2017. For purposes of this case only, Par accepts that date as the effective filing date.

34. Par Pharmaceutical is the assignee and owner of the '526, '209, and '785 patents (collectively, "the Asserted Patents"). EPIC is the exclusive licensee of the '526, '209, and '785 patents.

35. Craig Kenesky and Trisha Agrawal participated in the prosecution of the Asserted Patents and the '239 patent. Mr. Kenesky oversaw the work of Ms. Agrawal.

36. Christina Bradley was the examiner of record during prosecution of the Asserted Patents and the '239 patent.

37. The '526, '209, and '785 patents are listed in the FDA publication, the Approved Drug Products with Therapeutic Equivalence Evaluations (which is referred to as the "Orange Book"), with respect to Reformulated VASOSTRICT.

38. Par asserts that Eagle infringes claim 13 of the '526 patent. Claim 13 depends from claim 1 and reads as follows:

Claim 1: A method of increasing blood pressure in a human in need thereof, the method comprising:

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a) providing a pharmaceutical composition for intravenous administration comprising: i) from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically-acceptable salt thereof; ii) acetic acid; and iii) water,

wherein the pharmaceutical composition has a pH of 3.8;

b) storing the pharmaceutical composition at 2-8° C. for at least 4 weeks; and

c) intravenously administering the pharmaceutical composition to the human,

wherein the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute,

wherein the human is hypotensive,

wherein the pharmaceutical composition exhibits less than about 5% degradation after storage at 2-8° C. for about four weeks.

Claim 13: The method of claim 1, wherein the pharmaceutical composition exhibits less than 1% degradation after storage at 2-8° C. for about four weeks.

39. Par asserts that Eagle infringes claims 1, 3, 4, 5, and 7 of the '209 patent. Those claims read as follows:

Claim 1: A method of increasing blood pressure in a human in need thereof, the method comprising administering to the human a unit dosage form, wherein the unit dosage form comprises from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically acceptable salt thereof, wherein:

the unit dosage form has a pH of 3.7-3.9;

the unit dosage form further comprises impurities that are present in an amount of 0.9% - 1.7%, wherein the impurities have from about 85% to about 100% sequence homology to SEQ ID NO.: 1;

the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per

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minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute; and

the human is hypotensive.

Claim 3: The method of claim 1, wherein the impurities comprise SEQ ID NO.: 3, and SEQ ID NO.: 3 is present in the unit dosage form in an amount of 0.1%.

Claim 4: The method of claim 1, wherein the impurities comprise SEQ ID NO.: 4, and SEQ ID NO.: 4 is present in the unit dosage form in an amount of 0.2% to 0.4%.

Claim 5: The method of claim 1, wherein the impurities comprise SEQ ID NO.: 7, and SEQ ID NO.: 7 is present in the unit dosage form in an amount of 0.3% to 0.6%.

Claim 7: The method of claim 1, wherein the impurities comprise SEQ ID NO.: 2 and SEQ ID NO.: 4, and SEQ ID NO.: 2 is present in the unit dosage form in an amount of 0.1% to 0.3% and SEQ ID NO.: 4 is present in the unit dosage form in an amount of 0.2% to 0.4%.

40. Par asserts that Eagle infringes claims 1, 4, 5, and 8 of the '785 patent.

Those claims read as follows:

Claim 1: A pharmaceutical composition comprising, in a unit dosage form, from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically-acceptable salt thereof, wherein the unit dosage form further comprises impurities that are present in an amount of 0.9% to 1.7%, wherein the impurities have from about 85% to about 100% sequence homology to SEQ ID NO.: 1, and wherein the unit dosage form has a pH of 3.7-3.9.

Claim 4: The pharmaceutical composition of claim 1, wherein the impurities comprise SEQ ID NO.: 3, and SEQ ID NO.: 3 is present in the unit dosage form in an amount of 0.1%.

Claim 5: The pharmaceutical composition of claim 1, wherein the impurities comprise SEQ ID NO.: 4, and SEQ ID NO.: 4 is present in the unit dosage form in an amount of 0.2% to 0.4%.

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Claim 8: The pharmaceutical composition of claim 1, wherein the impurities comprise SEQ ID NO.: 2 and SEQ ID NO.: 4, and SEQ ID NO.: 2 is present in the unit dosage form in an amount of 0.1% to 0.3% and SEQ ID NO.: 4 is present in the unit dosage form in an amount of 0.2% to 0.4%.

42. As defined in the asserted '209 and '785 patents:

- SEQ ID NO.: 1 refers to vasopressin;
- SEQ ID NO.: 2 refers to Gly9-vasopressin (Gly9-AVP);
- SEQ ID NO.: 3 refers to Asp5-vasopressin (Asp5-AVP);
- SEQ ID NO.: 4 refers to Glu4-vasopressin (Glu4-AVP); and
- SEQ ID NO.: 7 refers to Acetyl-vasopressin (Acetyl-AVP).

41. Claim 13 of the '526 patent, claims 1, 3, 4, 5, and 7 of the '209 patent, and claims 1, 4, 5, and 8 of the '785 patent are referred to collectively as the “Asserted Claims.”

42. In its complaint, Par asserted three additional patents against Eagle: U.S. Patent Nos. 9,375,478 (“the '478 patent”), 9,744,239 (“the '239 patent”), and 9,937,223 (“the '223 patent”). During the course of the litigation, the parties stipulated to the dismissal of Par’s claims relating to the '478, '239, and '223 patents with prejudice, and Eagle’s defenses and counterclaims relating to the '478, '239, and '223 patents without prejudice. D.I. 164.

IV. EAGLE’S PROPOSED ANDA PRODUCT

43. Eagle submitted ANDA No. 211538 (“Eagle’s ANDA”) pursuant to 35 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and sale of a proposed generic vasopressin product, Vasopressin Injection USP, 20 units/1 mL (“Eagle’s Proposed ANDA Product”), identifying VASOSTRICT as the reference listed drug.

44. Pursuant to its ANDA, Eagle is seeking FDA approval to make, use, and sell its Proposed ANDA Product before expiration of the Asserted Patents.

45. Eagle’s ANDA includes Paragraph IV certifications to the Asserted Patents pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), certifying that Eagle believes the Asserted Patents are invalid or will not be infringed by the commercial manufacture, use, or sale of Eagle’s Proposed ANDA Product.

46. Eagle’s Proposed ANDA Product is formulated with the following components:

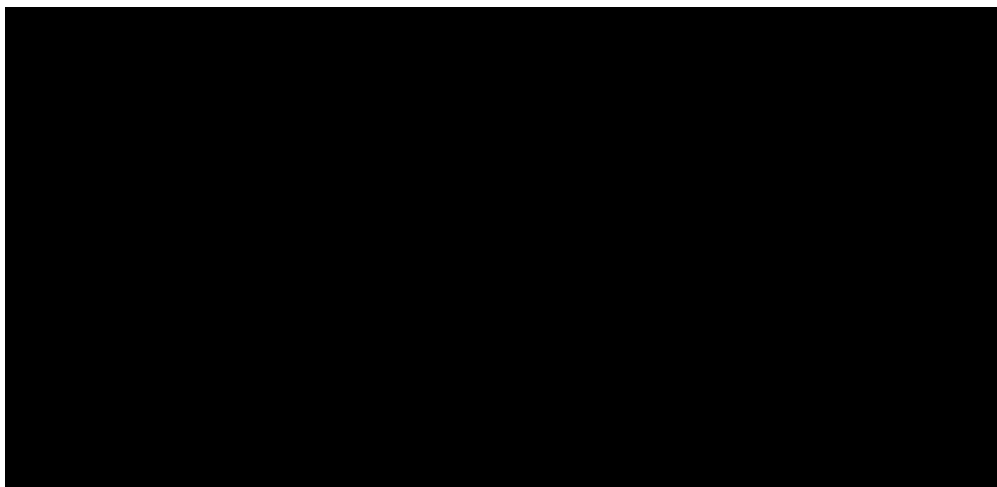


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47. Eagle's Proposed ANDA Product seeks approval for a shelf life of

[REDACTED]

[REDACTED]

[REDACTED] See, e.g., EAGLEVAS0043670 at 778 (DTX-174); *see also* DTX-331.

48. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

49. [REDACTED]

[REDACTED]

[REDACTED]

50. [REDACTED]

[REDACTED]

[REDACTED]

51. [REDACTED]

[REDACTED]

[REDACTED]

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52. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

53. [REDACTED]

[REDACTED]

[REDACTED]

54. In connection with its ANDA, Eagle has conducted release and stability testing on batches of its Proposed ANDA Product for pH, assay, and impurity levels [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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55. [REDACTED]

[REDACTED]

[REDACTED]

56. If approved, Eagle’s Proposed ANDA Product would, when sold, be packaged together with a package insert, the current proposed draft of which was produced at EAGLEVAS0059158-166 (see, e.g., DTX-662).

57. Eagle denies that its Proposed ANDA Product infringes any of the Asserted Claims.

V. CLAIM CONSTRUCTION

58. The parties stipulated that the claim term “vasopressin” should be construed to mean “arginine vasopressin as described in SEQ. ID. NO. 1 (see, e.g., ’239 patent, cols. 25-26)” with respect to each of the Asserted Patents. D.I. 61 at 12.

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59. The Court ordered that the '526 patent claim term “intravenously administering the pharmaceutical composition to the human” and the '209 patent claim term “administering to the human a unit dosage form” be given their “[p]lain and ordinary meaning; no construction necessary.” D.I. 71. No other claim term of the Asserted Patents was construed by the Court.

VI. EAGLE’S INVALIDITY DEFENSES

A. Anticipation/Obviousness

60. Eagle contends that the Asserted Claims are invalid as anticipated and/or obvious based on the below prior art references, in view of the state of the art, the knowledge and skill of a person of ordinary skill in the art, and other background:

Patent	Claim(s)	Grounds
'526 patent	13	<ol style="list-style-type: none"> 1) Anticipation/obviousness over Original VASOSTRICT with its prescribing information 2) Obviousness over PITRESSIN® with its prescribing information in view of WHO Standard (DTX-201), Russell 2008 (DTX-232), and Intravenous Medications 2013 (DTX-206) 3) Obviousness over PPC (DTX-136) in view of WHO Standard, Russell 2008, and Intravenous Medications 2013 4) Obviousness over the April 2014 VASOSTRICT Label (DTX-30 at PAR-VASO_0015576-583) 5) Obviousness over American Regent Vasopressin Injection with its prescribing information in view of Russell 2008 and Intravenous Medications 2013

Patent	Claim(s)	Grounds
'209 patent	1, 3, 4, 5, 7	1) Anticipation/obviousness over Original VASOSTRICT with its prescribing information 2) Obviousness over PITRESSIN with its prescribing information in view of Russell 2008 and Intravenous Medications 2013 3) Obviousness over PPC in view of Russell 2008 and Intravenous Medications 2013 4) Obviousness over the April 2014 VASOSTRICT Label 5) Obviousness over American Regent Vasopressin Injection with its prescribing information in view of Russell 2008 and Intravenous Medications 2013
'785 Patent	1, 4, 5, 8	1) Anticipation/obviousness over Original VASOSTRICT with its prescribing information 2) Anticipation/obviousness over PITRESSIN with its prescribing information 3) Obviousness over PPC 4) Obviousness over the April 2014 VASOSTRICT Label 5) Obviousness over American Regent Vasopressin Injection with its prescribing information

61. Par denies that the asserted prior art anticipates or renders obvious any of the Asserted Claims.

1. Prior Art

62. Original VASOSTRICT, PITRESSIN, and American Regent Vasopressin Injection products that were on sale and in public use are prior art to the Asserted Patents.

63. PITRESSIN [REDACTED]

[REDACTED]

[REDACTED]

64. PITRESSIN [REDACTED]

[REDACTED]

[REDACTED]

65. For purposes of this case only, Par does not dispute that the April 2014 (DTX-30 at PAR-VASO_0015576-583), September 2014 (DTX-46 at PAR-VASO_0014807-808), and May 2015 (DTX-132 at PAR-VASO_0014785-786) approved labels for Original VASOSTRICT are prior art to the Asserted Patents.

66. The January 2010 labeling for Pitressin (DTX-51) is prior art to the Asserted Patents.

67. The October 2012 labeling for Pitressin (DTX-178) is prior art to the Asserted Patents.

68. PPC (DTX-136) is prior art to the Asserted Patents.

69. *WHO International Standard: Arginine Vasopressin (AVP)*, Nat'l. Inst. for Biol. Standards & Control (Apr. 30, 2013) ("WHO Standard") (DTX-201) is prior art to the Asserted Patents.

70. A. Russell et al., *Vasopressin versus Norepinephrine Infusion in Patients with Septic Shock*, N. Eng. J. Med. 358(9):877-87 (2008) (“Russell 2008”) (DTX-232) is prior art to the Asserted Patents.

71. Intravenous Medications (B. L. Gahart & A. R. Nazareno et al., eds. 29th ed. 2013) (“Intravenous Medications 2013”) (DTX-206) is prior art to the Asserted Patents.

72. Adamsons et al, *The Stability of Natural and Synthetic Neurophysial Hormones in Vitro*, Endocrinology, 63(5):679-87 (1958) (“Adamsons”) (“PTX-153”) is prior art to the Asserted Patents.

73. W. Wang, *Instability, stabilization, and formulation of liquid protein pharmaceuticals*, International Journal of Pharmaceutics 185:129-188 (1999) (“Wang”) (PTX-381) is prior art to the Asserted Patents

74. M. Bi & J. Singh, *HPLC Method for Quantification of Arginine Containing Vasopressin*, J. Liq. Chrom. & Technol. 22(4):551-60 (1999) (“Bi 1999”) (DTX-248) is prior art to the Asserted Patents.

75. M. Bi & J. Singh, *Effect of buffer pH, buffer concentration and skin with or without enzyme inhibitors on the stability of [Arg⁸]-vasopressin*, International Journal of Pharmaceutics 197:87-93 (2000) (“Bi 2000”) (PTX-275) is prior art to the Asserted Patents.

76. L. Stratton et al., *Controlling Deamidation Rates in a Model Peptide: Effects of Temperature, Peptide Concentration, and Additives*, Journal of Pharmaceutical Sciences 90(12):2141-2148 (2001) (“Stratton”) (PTX-374) is prior art to the Asserted Patents.

77. Chang et al., Practical Approaches to Protein Formulation Development *in* Rational Design of Stable Protein Formulations (Carpenter et al. eds., 2002) (“Chang”) (DTX-247) is prior art to the Asserted Patents.

78. Protein Formulation & Delivery (2d ed., E. McNally et al. eds. 2008) (“McNally”) (DTX-274) is prior art to the Asserted Patents.

79. A. Hawe et al., Towards Heat-stable Oxytocin Formulations: Analysis of Degradation Kinetics and Identification of Degradation Products, Pharm. Res. 26(7):1679-88 (2009) (“Hawe 2009”) (DTX-175) is prior art to the Asserted Patents.

80. USP 32, U.S. Pharmacopeia, National Formulary (2009) (“USP 2009”) (DTX-135) is prior art to the Asserted Patents.

81. Manning et al., Stability of Protein Pharmaceuticals: An Update, Pharm. Research, 27:544–75 (2010) (“Manning”) (DTX-254) is prior art to the Asserted Patents.

82. Avanti, Innovative Strategies for Stabilization of Therapeutic Peptides in Aqueous Formulation (2012) (“Avanti 2012”) (DTX-263) is prior art to the Asserted Patents.

83. Biopharmaceutics Review for NDA 204485, Center for Drug Evaluation and Research (March 2013) (“FDA Biopharmaceutics Review”) (PTX-146) is prior art to the Asserted Patents.

84. Chemistry Review(s) for NDA 204485, Center for Drug Evaluation and Research (“FDA Chemistry Review”) (PTX-309) is prior art to the Asserted Patents.

B. Section 112

85. Eagle contends that the Asserted Claims are invalid for lack of written description, lack of enablement, and indefiniteness under 35 U.S.C. § 112 based on the following grounds:

- 1) The '526 patent lacks written description of the composition recited in claim 1 that is stored at 2-8°C for at least four weeks and that exhibits “less than 1% degradation after storage at 2-8° C. for about four weeks”;
- 2) The '526, '209, and '785 patents lack written description for the full scope of the claimed compositions;

- 3) The '209 and '785 patents lack written description of the claimed composition with "0.1%" SEQ ID NO.: 3 as recited in claim 3 of the '209 patent and claim 4 of the '785 patent;
- 4) The '526, '209, and '785 patents lack enablement for the full scope of the claimed compositions;
- 5) Claim 13 of the '526 patent is indefinite with respect to the following limitation: "less than [X]% degradation after storage at 2-8° C. for about four weeks"; and
- 6) The '526, '209, and '785 patents are indefinite with respect to when to measure pH.

86. Par denies that Eagle's Section 112 invalidity theories render any of the Asserted Claims invalid.

VII. EAGLE'S UNENFORCEABILITY DEFENSE

87. Eagle contends that the Asserted Claims are unenforceable for inequitable conduct based on the alleged intentional withholding of material prior art during prosecution of the Asserted Patents, and the alleged submission to the PTO of unmistakably false declarations during prosecution of the '239 patent.

88. Par denies that Eagle's inequitable conduct theories render any of the Asserted Claims unenforceable.

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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

<p>PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC and ENDO PAR INNOVATION COMPANY, LLC,</p> <p>Plaintiffs,</p> <p>v.</p> <p>EAGLE PHARMACEUTICALS INC.,</p> <p>Defendant.</p>	<p>C.A. No. 18-cv-823-CFC</p> <p>[REDACTED]</p>
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PLAINTIFFS' STATEMENT OF CONTESTED ISSUES OF FACT

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Pursuant to Local Rule 16.3(c)(4), Plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC and Endo Par Innovation Company, LLC (collectively “Plaintiffs”) submit the following statement of issues of fact that remain to be litigated. The following statements are meant to serve as an overview of the contested facts to be litigated at trial. Accordingly, Par reserves the right to prove additional details regarding the below facts that have been identified throughout the discovery process including facts identified in expert reports. Plaintiffs further intend to offer evidence to rebut evidence offered by Defendants. Plaintiffs reserve the right to modify or amend this Statement to the extent necessary to reflect any future rulings by the Court, and to supplement or amend this Statement to fairly respond to any new issues that Defendants may raise. To the extent Plaintiffs’ statement of the issues of law that remain to be litigated, which is submitted as **Exhibit 4** hereto, contains issues of fact, those issues are incorporated herein by reference. Moreover, if any issue of fact identified below should properly be considered an issue of law, then such statement should be considered to be part of Plaintiffs’ statement of issues of law that remain to be litigated. Plaintiffs incorporate by reference their expert reports in support of any proof to be presented by expert testimony. Plaintiffs’ Statement of Intended Proofs is submitted as **Exhibit 13** hereto.

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As an initial matter, Par believes Eagle's Statement of Issues of Fact that Remain to Be Litigated goes well beyond the Court's requirements. Instead of identifying issues, Eagle sets forth a detailed statement of alleged facts, rather than just identifying the issues of fact to be litigated. In an abundance of caution, Par responds with its own detailed statement. Par's statement, however, is not intended to be a comprehensive list of all facts that Par will prove at trial, and is not intended to be a point-by-point rebuttal of every alleged fact in Eagle's Statement. Par reserves the right to prove additional factual matter at trial as necessary to rebut Eagle's presentation.

I. PERSON OF ORDINARY SKILL IN THE ART

1. A person of ordinary skill in the art ("POSA") to whom the Asserted Patents are directed would have a Master's, Pharm.D., or Ph.D. in the field of pharmaceutical sciences or a related discipline and several years of experience in the development of pharmaceutical dosage forms. The amount of experience would vary in relation to the level of formal education and depth of experience with pharmaceutical dosage development. A person of ordinary skill in the art may also have less formal education and a greater amount of experience. Further, a POSA would have had access to and would have worked in collaboration with persons who have several years of experience in the formulation of drug products

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as well as other professionals in the drug development field, such as pharmacologists, chemists, biologists, or clinicians.

II. TECHNOLOGY BACKGROUND

2. Peptide drugs can undergo various chemical degradation processes including hydrolysis, oxidation, isomerization, polymerization, and photochemical decomposition, which result in a decrease in amount of the active pharmaceutical ingredient (“API”). These processes can occur after synthesis of the API, during storage of the API prior to drug product manufacture, during manufacture of the drug product, and over the shelf-life of the manufactured drug product, resulting in the generation and growth of unwanted impurities in the drug product.

3. FDA requires stability testing before drug product approval. Stability testing is the means for determining the appropriate shelf-life for a new product, and assuring that subsequent batches of a product meet the specified shelf-life. It is conducted on (among other things) samples of the final packaged pharmaceutical product. The packages are either stored under the label-specified storage conditions or under harsher conditions. Samples are withdrawn periodically and tested for, among other things, loss of the active ingredient, pH, and/or the presence of impurities. The results are used to set the storage conditions and the product specifications, which include pH, active ingredient assay, and impurities.

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4. In view of the prior art, a POSA would have understood that the levels of impurities and amount of degradation in a given formulation can be affected by many different factors, including, for example, how the formulation is manufactured, storage conditions (such as temperature), the amount of time the formulation is stored, the pH of the formulation, as well as the other ingredients or excipients in a formulation.

5. Because of degradation of vasopressin, the levels of impurities in vasopressin formulations increase over time.

6. As of the filing dates of the Asserted Patents, there were many different strategies for trying to improve peptide stability, including without limitation: pH optimization; ionic strength optimization; cosolvents; optimizing buffer choice and concentration; inert gas overlay; inclusion of antioxidants and/or chelating agents; selection of appropriate polyols; protection against radiant energy; and inclusion of various reported peptide stabilizers.

7. pH is the measure of the acidity or alkalinity of a solution. The pH value is related to the concentration of hydrogen ions in a solution. pH is logarithmic so that every 1 unit change represents an order of magnitude change in the concentration of acid. A 0.1 unit pH difference represents a 26% change in the concentration of acid. And, a 0.2 unit pH difference represents a 58% change in

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the concentration of acid. A 2 unit pH difference represents a hundred-fold difference in the concentration of acid.

8. A POSA would have understood 2-8°C to refer to refrigerated temperature in the context of storing vasopressin formulations.

9. A POSA would have understood 15-30°C to refer to room temperature in the context of storing vasopressin formulations.

III. TERMINOLOGY

10. Claim 13 of the '526 patent requires that “the pharmaceutical composition exhibits less than 1% degradation after storage at 2-8°C for about four weeks.” This limitation is referred to herein as the “degradation limitation.”

11. Claim 13 of the '526 patent requires “storing the pharmaceutical composition at 2-8°C for at least 4 weeks.” This limitation is referred to herein as the “storing limitation.”

12. Claim 13 of the '526 patent requires a pH of 3.8 and the asserted '209 and '785 claims require a pH of 3.7-3.9. These limitations are referred to herein collectively as the “pH limitations.”

13. The asserted '209 and '785 claims require “impurities that are present in an amount of 0.9% to 1.7%, wherein the impurities have from about 85% to about 100% sequence homology to SEQ ID NO.: 1.” Dependent claims 3, 4, 5, and 7 of the '209 patent and claims 4, 5, and 8 of the '785 patent further narrow the

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amount of certain impurities present—namely, 0.1-0.3% SEQ ID NO. 2, 0.1% SEQ ID NO. 3, and 0.2-0.4% SEQ ID NO. 4. Below is a chart that summarizes these claimed values:

Impurity	Claimed Range	Claims
Impurities have from about 85% to about 100% sequence homology to SEQ ID NO. 1	0.9 – 1.7%	All claims of '209 and '785 patents
SEQ ID NO. 2 (Gly9-AVP)	0.1 – 0.3%	'209 patent claim 7 '785 patent claim 8
SEQ ID NO. 3 (Asp5-AVP)	0.1%	'209 patent claim 3 '785 patent claims 4
SEQ ID NO. 4 (Glu4-AVP)	0.2 – 0.4%	'209 patent claims 4 and 7 '785 patent claims 5 and 8
SEQ ID NO. 7 (Acetyl-AVP)	0.3 – 0.6%	'209 patent claim 5

These limitations are referred to herein collectively as the “impurity limitations.”

14. The asserted '526 and '209 patents contain the following claim elements that relate to the clinical use of vasopressin compositions to increase blood pressure in hypotensive patients, and the preparation and handling of those compositions in a clinical setting:

- Intravenous administration;
- Using vasopressin to increase blood pressure in a hypotensive patient; and
- Administering doses of about 0.01 to about 0.1 units/minute.

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These limitations are referred to herein collectively as the “clinical limitations.”

IV. INFRINGEMENT

15. Whether Eagle’s submission of its ANDA to the FDA constitutes infringement of the Asserted Patents pursuant to 35 U.S.C. § 271(e)(2).

16. Whether the commercial manufacture, use, offer for sale, sale, and/or importation of any of Eagle’s Proposed ANDA Products—when stored and used according to the instructions provided in its accompanying package insert before expiration of the Asserted Patents—is likely to directly or indirectly infringe the Asserted Patents pursuant to 35 U.S.C. § 271(a) and/or (b).

17. Whether, in the event Eagle’s ANDA is approved by the FDA, Eagle would be authorized to commercially manufacture and sell any products that, when stored and used according to the instructions provided in its accompanying package insert before expiration of the Asserted Patents, would be likely to infringe the Asserted Patents pursuant to 35 U.S.C. § 271(a) and/or (b) at any time prior to the expiration of the proposed shelf-life of the product.

18. Whether any infringing use of Eagle’s proposed ANDA products would be performed by a single person or entity.

19. Whether any infringing use of Eagle’s proposed ANDA products would be attributable to a single person or entity.

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20. Whether Eagle is likely to induce any infringing use of its proposed ANDA products by others.

'785 Patent

21. Whether any of Eagle's proposed ANDA products are likely to satisfy each limitation of asserted claims 1, 4, 5, and/or 8 of the '785 patent at any time prior to the expiration of the proposed shelf-life of the product.

22. Whether the commercial manufacture, use, offer for sale, sale, and/or importation of any of Eagle's Proposed ANDA Products—when stored and used according to the instructions provided in its accompanying package insert—is likely to directly or indirectly infringe asserted claims 1, 4, 5, and/or 8 of the '785 patent.

23. Whether, in the event Eagle's ANDA is approved by the FDA, Eagle would be authorized to commercially manufacture and sell any products that, when stored and used according to the instructions provided in its accompanying package insert, would be likely to infringe asserted claims 1, 4, 5, and/or 8 of the '785 patent at any time prior to the expiration of the proposed shelf-life of the product.

24. Whether Eagle will induce any infringement of the '785 patent by others.

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'209 Patent

25. Whether any of Eagle's proposed ANDA products are likely to satisfy each of the formulation-related limitations¹ of asserted claims 1, 3, 4, 5, and/or 7 of the '209 patent at any time prior to the expiration of the proposed shelf-life of the product.

26. Whether the commercial use of any of Eagle's Proposed ANDA Products—when used and administered according to the instructions provided in its accompanying package insert—is likely to infringe asserted claims 1, 3, 4, 5, and/or 7 of the '209 patent.

27. Whether, in the event Eagle's ANDA is approved by the FDA, Eagle would be authorized to commercially manufacture and sell any products that, when used and administered according to the instructions provided in its accompanying package insert, would be likely to infringe asserted claims 1, 3, 4, 5, and/or 7 of the '209 patent at any time prior to the expiration of the proposed shelf-life of the product.

28. Whether Eagle will induce any infringement of the '209 patent by others.

¹ Par refers to “formulation-related limitations” consistent with how those terms were defined and addressed in the infringement expert reports of Dr. Zlatan Coralic and Dr. Lee Kirsch served in this case.

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'526 Patent

29. Whether any of Eagle's proposed ANDA products are likely to satisfy each of the formulation-related limitations of asserted claim 13 of the '526 patent at any time prior to the expiration of the proposed shelf-life of the product.

30. Whether the commercial use of any of Eagle's Proposed ANDA Products—when used and administered according to the instructions provided in its accompanying package insert—is likely to infringe asserted claim 13 of the '526 patent.

31. Whether, in the event Eagle's ANDA is approved by the FDA, Eagle would be authorized to commercially manufacture and sell any products that, when used and administered according to the instructions provided in its accompanying package insert, would be likely to infringe asserted claim 13 of the '526 patent at any time prior to the expiration of the proposed shelf-life of the product.

32. Whether the steps of the claimed method of asserted claim 13 of the '526 patent are likely ever to be performed by a single person or entity.

33. Whether the performance of the steps of the claimed method of asserted claim 13 of the '526 patent are likely ever to be attributable to a single person or entity.

34. Whether Eagle will induce any infringement of the '526 patent by others.

EXHIBIT 2

V. VALIDITY²

A. State of the Prior Art

35. Vasopressin products had a long history of successful and safe use in the prior art.

36. There were no reported disclosures in the prior art about the degree of degradation or levels of impurities within marketed vasopressin products.

37. Although the technology needed to measure and characterize vasopressin degradation products was well known in the prior art, there were no reported disclosures about the characterization of the degradation products of vasopressin.

38. There were no reported efforts in the prior art to modify a vasopressin formulation to limit the generation of any specific impurities.

² The Sections herein relating to Validity and Unenforceability are set forth in response to the corresponding Statement of Issues of Fact that Remain to be Litigated from Eagle. Rather than setting forth the contested issues of fact, Eagle has provided a putative statement of asserted facts. Par hereby responds to those statements by identifying facts it contends to be relevant to Eagle's allegations of invalidity and unenforceability, and which demonstrate that Eagle has failed to prove by clear and convincing evidence that any Asserted Claim is either invalid or unenforceable. However, Par has not attempted to respond on a point-by-point basis to all of the facts set forth in Eagle's statement, and it should not be interpreted as such. Any failure to respond to any particular alleged fact set forth in Eagle's statement is not an admission as to the truth of that fact or an indication that Par does not dispute it.

EXHIBIT 2

39. There were no reported issues, problems, or concerns in the prior art with the degree of degradation or levels of impurities within vasopressin products.

40. There were no reported issues, problems, or concerns in the prior art with the stability of vasopressin products, such as Original VASOSTRICT, PITRESSIN, American Regent Vasopressin Injection, or the vasopressin product disclosed in PPC.

41. The optimal pH for vasopressin formulations had already been determined as of the filing dates of the Asserted Patents, and the optimal pH was believed to be below that of the claimed ranges. *See, e.g.*, Adamsons (PTX-153); Bi 2000 (PTX-275), FDA Biopharmaceutics Review (PTX-146); FDA Chemistry Review (PTX-309).

B. Art asserted by Eagle

42. Eagle contends that the Asserted Claims are invalid as anticipated and/or obvious based on the following grounds:

Patent	Claim(s)	Grounds
'526 patent	Claim 13	1) Anticipation/Obviousness over Original VASOSTRICT with its prescribing information 2) Obviousness over PITRESSIN with its prescribing information in view of WHO Standard, Russell 2008, and Intravenous Medications 2013 3) Obviousness over PPC in view of WHO Standard, Russell 2008, and Intravenous Medications 2013 4) Obviousness over the April 2014 VASOSTRICT Label

EXHIBIT 2

Patent	Claim(s)	Grounds
		5) Obviousness over American Regent Vasopressin Injection with its prescribing information in view of Russell 2008 and Intravenous Medications 2013
'209 patent	Claims 1, 3, 4, 5, 7	1) Anticipation/Obviousness over Original VASOSTRICT with its prescribing information 2) Obviousness over PITRESSIN with its prescribing information in view of Russell 2008 and Intravenous Medications 2013 3) Obviousness over PPC in view of Russell 2008 and Intravenous Medications 2013 4) Obviousness over the April 2014 VASOSTRICT Label 5) Obviousness over American Regent Vasopressin Injection with its prescribing information in view of Russell 2008 and Intravenous Medications 2013
'785 Patent	Claims 1, 4, 5, 8	1) Anticipation/Obviousness over Original VASOSTRICT with its prescribing information 2) Anticipation/Obviousness over PITRESSIN with its prescribing information 3) Obviousness over PPC 4) Obviousness over the April 2014 VASOSTRICT Label 5) Obviousness over American Regent Vasopressin Injection with its prescribing information

1. Original VASOSTRICT

43. [REDACTED]

[REDACTED]

[REDACTED]

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44. [REDACTED]

[REDACTED]

45. [REDACTED]

[REDACTED]

46. [REDACTED]

[REDACTED]

47. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

	[REDACTED]							
	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]

48. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

EXHIBIT 2

2. April 2014 VASOSTRICT Label

49. The April 2014 VASOSTRICT Label was before the patent examiner during prosecution of the Asserted Patents.

50. Original VASOSTRICT was first sold with the VASOSTRICT label that was approved in September 2014. No Original VASOSTRICT was sold with the April 2014 VASOSTRICT Label.

51. The April 2014 VASOSTRICT Label did not disclose that the pH of Original VASOSTRICT was within the claimed range of 3.7-3.9.

52. The April 2014 VASOSTRICT Label did not disclose the amount of degradation within the disclosed Original VASOSTRICT product or any data for calculating the degradation of vasopressin.

53. The April 2014 VASOSTRICT Label did not disclose any impurity levels for the disclosed Original VASOSTRICT product.

54. The April 2014 VASOSTRICT Label instructed users to store the Original VASOSTRICT product between 15°C and 25°C. It did not instruct users to store Original VASOSTRICT at the claimed 2-8°C for at least 4 weeks.

EXHIBIT 2

3. PITRESSIN

55. Vasopressin products were sold in the United States under the trade name PITRESSIN by Par and its predecessors-in-interest (including JHP Pharmaceuticals, King Pharma, and Parke-Davis).

56. PITRESSIN was indicated for the prevention and treatment of postoperative abdominal distention, in abdominal roentgenography to dispel interfering gas shadows and in diabetes insipidus. PITRESSIN was not indicated for the treatment of hypotensive patients.

57. PITRESSIN was sold for over 100 years. Par stopped selling PITRESSIN in the fall of 2014.

58. PITRESSIN was known in the prior art to be safe and effective.

59. PITRESSIN was known in the prior art to be stable.

60. PITRESSIN had a shelf life of 24 months at room temperature.

61. The labels for PITRESSIN instructed users to store the product at room temperature. They did not instruct users to store PITRESSIN at the claimed 2-8°C for at least 4 weeks.

62. The Pitressin 2012 Label (DTX-178) was before the patent examiner during prosecution of the Asserted Patents.

63. Eagle's expert identified PITRESSIN [REDACTED]s being sold before the filing dates of the Asserted Patents.

EXHIBIT 2

64. PITRESSIN [REDACTED] was manufactured on [REDACTED].

65. PITRESSIN from [REDACTED] was sold starting on [REDACTED].

66. There is no measurement of a pH value within the claimed ranges for PITRESSIN from [REDACTED] from the time when it was first sold.

67. There is no evidence that PITRESSIN from [REDACTED] with a pH value within the claimed ranges was ever administered to a patient.

68. PITRESSIN [REDACTED] was manufactured on [REDACTED].

69. PITRESSIN from [REDACTED] was sold starting on [REDACTED].

70. There is no measurement of a pH value within the claimed ranges for PITRESSIN from [REDACTED] from the time when it was first sold.

71. There is no evidence that PITRESSIN from [REDACTED] with a pH value within the claimed ranges was ever administered to a patient.

72. The PITRESSIN formulation is different than the Original VASOSTRICT formulation. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

EXHIBIT 2

4. PPC

73. The PPC reference is the June 2009 product insert for Pharmaceutical Partners of Canada Inc.'s vasopressin product.

74. PPC was before the patent examiner during prosecution of the Asserted Patents.

75. The vasopressin product disclosed in PPC was indicated for the prevention and treatment of postoperative abdominal distention, in abdominal roentgenography to dispel interfering gas shadows and in diabetes insipidus. It was not indicated for the treatment of hypotensive patients.

76. PPC disclosed that the pH of the disclosed vasopressin product was adjusted to pH 2.5-4.5 with glacial acetic acid and/or sodium hydroxide.

77. PPC did not disclose the amount of degradation within the disclosed vasopressin product or any data for calculating degradation of vasopressin.

78. PPC did not disclose any impurity levels for the disclosed vasopressin product.

79. PPC instructed users to store the disclosed vasopressin product between 15 and 30°C. It did not instruct users to store the product at the claimed 2-8°C for at least 4 weeks.

EXHIBIT 2

5. American Regent Vasopressin Injection

80. American Regent Vasopressin Injection was indicated for the prevention and treatment of postoperative abdominal distention, in abdominal roentgenography to dispel interfering gas shadows and in diabetes insipidus. It was not indicated for the treatment of hypotensive patients.

81. The American Regent Label, dated 2011 (DTX-246), was before the patent examiner during prosecution of the Asserted Patents.

82. The American Regent Label taught that the pH of American Regent Vasopressin Injection was adjusted to pH 2.5-4.5.

83. It was not known in the prior art that any lot of American Regent Vasopressin Injection had a [REDACTED].

84. Eagle's expert identified American Regent Vasopressin Injection [REDACTED] as being sold before the filing dates of the Asserted Patents.

85. American Regent Vasopressin Injection [REDACTED] was manufactured on [REDACTED].

86. American Regent Vasopressin Injection from [REDACTED] was commercially shipped on [REDACTED].

87. American Regent Vasopressin Injection from [REDACTED] expired in January 1998.

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88. [REDACTED]

[REDACTED]

89. [REDACTED]

[REDACTED]

[REDACTED]

90. [REDACTED]

[REDACTED]

91. American Regent Vasopressin Injection contained sodium chloride. Sodium chloride is a neutral salt which can affect drug stability by primary and/or secondary kinetic salt effects.

92. [REDACTED]

[REDACTED]

93. Before the filing dates of the Asserted Patents, [REDACTED]

[REDACTED]

[REDACTED]

6. WHO Standard

94. The WHO Standard is directed to the WHO international standard for vasopressin to be used as a calibrant for arginine vasopressin bioassays.

95. The vasopressin preparation disclosed in the WHO Standard is not for administration to humans.

EXHIBIT 2

96. The vasopressin preparation disclosed in the WHO Standard is made from a lyophilized solution containing vasopressin, human serum albumin, and N/200 citric acid.

C. Anticipation

97. Whether Eagle can demonstrate by clear and convincing evidence that each of the Asserted Claims of the '526, '209, and '785 patents is invalid as anticipated by the sales and use of Original VASOSTRICT before the filing dates of the Asserted Patents.

98. Whether Eagle can demonstrate by clear and convincing evidence that any Original VASOSTRICT product contained every limitation of each of the Asserted Claims when it was on sale or in public use before the filing dates of the Asserted Patents.

99. Whether Eagle can demonstrate by clear and convincing evidence the pH, assay, and impurity properties of any Original VASOSTRICT product when it was on sale or in public use before the filing dates of the Asserted Patents.

100. Whether Eagle can demonstrate by clear and convincing evidence that any Original VASOSTRICT product had a pH of 3.7, 3.8, or 3.9 when it was on sale or in public use before the filing dates of the Asserted Patents.

EXHIBIT 2

101. Whether Eagle can demonstrate by clear and convincing evidence that any Original VASOSTRICT product had a pH of 3.7, 3.8, or 3.9 when it was administered to a patient before the filing dates of the Asserted Patents.

102. Whether Eagle can demonstrate by clear and convincing evidence that any Original VASOSTRICT product satisfied the degradation and impurity limitations of the Asserted Claims when it was on sale or in public use before the filing dates of the Asserted Patents.

103. Whether Eagle can demonstrate by clear and convincing evidence that any Original VASOSTRICT product satisfied the degradation and impurity limitations of the Asserted Claims when it was administered to a patient before the filing dates of the Asserted Patents.

104. Whether Eagle can demonstrate by clear and convincing evidence that the degradation and impurity limitations of the Asserted Claims were inherent properties of Original VASOSTRICT.

105. Whether Eagle can demonstrate by clear and convincing evidence that the degradation limitation of '526 patent claim 13 is necessarily present in a formulation that has from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin, acetic acid, water, and a pH of 3.8.

106. Whether Eagle can demonstrate by clear and convincing evidence that the impurity limitations of the '209 and '785 patents are necessarily present in a

EXHIBIT 2

formulation that has from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin and a pH of 3.7-3.9.

107. Whether Eagle can demonstrate by clear and convincing evidence that

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

108. Whether Eagle can demonstrate by clear and convincing evidence that each of the asserted '785 claims is invalid as anticipated by the sales and use of PITRESSIN before the filing date of the '785 patent.

109. Whether Eagle can demonstrate by clear and convincing evidence that any PITRESSIN product contained every limitation of each of the asserted '785 claims when it was on sale or in public use before the filing date of the '785 patent.

110. Whether Eagle can demonstrate by clear and convincing evidence the pH, assay, and impurity properties of any PITRESSIN product when it was on sale or in public use before the filing dates of the Asserted Patents.

111. Whether Eagle can demonstrate by clear and convincing evidence that any PITRESSIN product, including PITRESSIN from [REDACTED], had a pH of 3.7, 3.8, or 3.9 when it was on sale or in public use before the filing dates of the Asserted Patents.

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112. Whether Eagle can demonstrate by clear and convincing evidence that any PITRESSIN product, including PITRESSIN from [REDACTED], had a pH of 3.7, 3.8, or 3.9 when it was administered to a patient before the filing dates of the Asserted Patents.

113. Whether Eagle can demonstrate by clear and convincing evidence that any PITRESSIN product, including PITRESSIN from [REDACTED], satisfied the degradation and impurity limitations of the Asserted Claims when it was on sale or in public use before the filing dates of the Asserted Patents.

114. Whether Eagle can demonstrate by clear and convincing evidence that any PITRESSIN product, including PITRESSIN from [REDACTED], satisfied the degradation and impurity limitations of the Asserted Claims when it was administered to a patient before the filing dates of the Asserted Patents.

115. Whether Eagle can demonstrate by clear and convincing evidence that the degradation and impurity limitations were inherent properties of PITRESSIN.

116. Whether Eagle can demonstrate by clear and convincing evidence that

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

EXHIBIT 2

D. Obviousness

117. Whether Eagle can demonstrate by clear and convincing evidence that each of the Asserted Claims is invalid as obvious in view of any of its proposed prior art combinations.

118. Plaintiffs incorporate the issues of fact listed above in the Anticipation section.

119. Whether Eagle can demonstrate by clear and convincing evidence that each claim limitation of the Asserted Claims was in the prior art.

120. Whether Eagle can demonstrate by clear and convincing evidence the pH, assay, and impurity properties of any American Regent Vasopressin Injection product when it was on sale or in public use before the filing dates of the Asserted Patents.

121. Whether Eagle can demonstrate by clear and convincing evidence that any American Regent Vasopressin Injection product satisfied the degradation and impurity limitations of the Asserted Claims when it was on sale or in public use before the filing dates of the Asserted Patents.

122. Whether Eagle can demonstrate by clear and convincing evidence that any American Regent Vasopressin Injection product satisfied the degradation and impurity limitations of the Asserted Claims when it was administered to a patient before the filing dates of the Asserted Patents.

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123. Whether Eagle can demonstrate by clear and convincing evidence that the degradation and impurity limitations were inherent properties of American Regent Vasopressin Injection or the vasopressin product disclosed in PPC.

124. Whether Eagle can demonstrate by clear and convincing evidence that the pH, degradation, and impurity limitations were inherent properties of the April 2014 VASOSTRICT Label.

125. Whether Eagle can demonstrate by clear and convincing evidence that the pH, degradation, impurity, storing, and clinical limitations are obvious in view of the prior art.

126. Whether Eagle can demonstrate by clear and convincing evidence which particular teachings in the asserted prior art references would have been combined to achieve the claimed inventions.

127. Whether Eagle can demonstrate by clear and convincing evidence that a POSA would have been motivated to modify or combine the prior art to make the claimed inventions in the manner that Eagle proposes.

128. Whether Eagle can demonstrate by clear and convincing evidence that a POSA would have been motivated to select any Original VASOSTRICT, PITRESSIN, or American Regent Vasopressin Injection product, or the April 2014 VASOSTRICT Label or PPC, as a starting point to make the claimed inventions.

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129. Whether the stability of Original VASOSTRICT, PITRESSIN, American Regent Vasopressin Injection, or the vasopressin product disclosed in PPC was an issue, concern, or problem to be solved in the prior art.

130. Whether Eagle can demonstrate by clear and convincing evidence that a POSA would have been motivated to improve the stability of Original VASOSTRICT, PITRESSIN, American Regent Vasopressin Injection, or the vasopressin product disclosed in PPC.

131. Whether Eagle can demonstrate by clear and convincing evidence that a POSA would have been motivated to modify the formulation of Original VASOSTRICT, PITRESSIN, American Regent Vasopressin Injection, or the vasopressin product disclosed in PPC to achieve maximum stability.

132. Whether Eagle can demonstrate by clear and convincing evidence that a POSA would have been motivated to analyze the pH-dependent stability of Original VASOSTRICT, PITRESSIN, American Regent Vasopressin Injection, or the vasopressin product disclosed in PPC and optimize for stability.

133. Whether pH studies for vasopressin formulations in the prior art would have directed a POSA away from the pH values claimed in the Asserted Patents (3.8 and 3.7-3.9) and towards a lower pH value.

134. Whether the prior art taught away from the pH values claimed in the Asserted Patents.

EXHIBIT 2

135. What the prior art taught was the optimal pH for the stability of vasopressin.

136. Whether, in view of the prior art, a POSA would have considered it unproductive to vary the pH for prior art vasopressin formulations.

137. Whether, in view of the prior art, a POSA would have considered a pH optimization study for vasopressin formulations to be unlikely to identify an optimal pH within the claimed ranges.

138. Whether because the pH of vasopressin formulations was understood to have already been optimized, there would have been a reason for a POSA to “further optimize” the pH.

139. Whether there was any appreciation in the prior art that the claimed pH values provided a vasopressin product with an enhanced stability and impurity profile.

140. Whether, even assuming that there was a motivation to modify prior art vasopressin formulations, a POSA would have considered strategies other than optimizing the pH, including without limitation: ionic strength optimization; cosolvents; optimizing buffer choice and concentration; inert gas overlay; inclusion of antioxidants and/or chelating agents; selection of appropriate polyols; protection against radiant energy; and inclusion of various reported peptide stabilizers.

EXHIBIT 2

141. Whether reduced impurity levels within vasopressin products was an actual perceived need amongst skilled artisans in the prior art.

142. Whether Eagle can demonstrate by clear and convincing evidence that a POSA would have been motivated to reduce the levels of impurities within Original VASOSTRICT, PITRESSIN, American Regent Vasopressin Injection, or the vasopressin product disclosed in PPC.

143. Whether Eagle can demonstrate by clear and convincing evidence that a POSA would have been motivated to store PITRESSIN, American Regent Vasopressin Injection, the Original VASOSTRICT product disclosed in the April 2014 VASOSTRICT Label, or the vasopressin product disclosed in PPC at 2-8°C for at least 4 weeks.

144. Whether Eagle can demonstrate by clear and convincing evidence that a POSA would have been motivated to treat patients and administer PITRESSIN, American Regent Vasopressin Injection, or the vasopressin product disclosed in PPC according to the clinical limitations.

145. Whether Eagle can demonstrate by clear and convincing evidence that there would have been a reasonable expectation of success in making the claimed inventions in the manner that Eagle proposes.

EXHIBIT 2

146. Whether Eagle can demonstrate by clear and convincing evidence that there would have been a reasonable expectation of success that the claimed pH values would enhance the stability of vasopressin.

147. Whether, in view of the prior art, a POSA would have had any basis to believe that the claimed pH values would improve the stability of vasopressin.

148. Whether Eagle can demonstrate by clear and convincing evidence that there would have been a reasonable expectation of success that a pH optimization study would identify a pH value within the claimed pH values as the optimal pH for vasopressin formulations.

149. Whether Eagle can demonstrate by clear and convincing evidence that a POSA actually would have identified the claimed pH values as optimal for the stability of vasopressin.

150. Whether the claimed pH values are presumptively obvious over the prior art ranges.

151. Whether any presumption of obviousness of the claimed pH values in view of the prior art ranges is rebutted by the teaching away in the prior art from the claimed pH values, the criticality of the claimed pH values, and other reasons supporting the non-obviousness of the Asserted Claims.

152. Whether Eagle can demonstrate by clear and convincing evidence that there would have been a reasonable expectation of success in achieving the

EXHIBIT 2

claimed vasopressin formulation that meets the degradation and impurity limitations.

153. Whether the prior art gave direction as to which, if any, of the many strategies for potentially reducing impurity levels would be successful within vasopressin formulations.

154. Whether the prior art gave direction as to the degree to which impurity levels needed to be reduced to reach the levels claimed in the impurity limitations.

155. What insight, if any, the prior art provided about the degradation pathways and degradation products of vasopressin.

156. Whether a POSA would have found guidance from the WHO Standard about the storage conditions or formulation properties (e.g., pH) of a vasopressin pharmaceutical composition intended for administration.

157. Whether Eagle has shown by clear and convincing evidence that Lithuanian Patent No. 4487 is prior art to the Asserted Patents.

158. Whether a POSA would have found guidance in Lithuanian Patent No. 4487, which is directed to a naturally derived arginine vasopressin formulation, about the formulation and stability properties of a synthetic arginine vasopressin formulation.

159. Whether the claimed formulations showed superior results in terms of assay and impurity levels compared with the Original VASOSTRICT formulation.

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E. Section 112

160. Eagle contends that the Asserted Claims are invalid for lack of written description, lack of enablement, and indefiniteness based on the following grounds:

- 1) The '526 patent lacks written description of the composition recited in claim 1 that is stored at 2-8°C for at least four weeks and that exhibits “less than 1% degradation after storage at 2-8° C. for about four weeks”;
- 2) The '526, '209, and '785 patents lack written description for the full scope of the claimed compositions;
- 3) The '209 and '785 patents lack written description of the claimed composition with “0.1%” SEQ ID NO.: 3 as recited in claim 3 of the '209 patent and claim 4 of the '785 patent;
- 4) The '526, '209, and '785 patents lack enablement for the full scope of the claimed compositions;
- 5) Claim 13 of the '526 patent is indefinite with respect to the following limitation: “less than [X]% degradation after storage at 2-8° C. for about four weeks”; and
- 6) The '526, '209, and '785 patents are indefinite with respect to when to measure pH.

1. Lack of Written Description

161. Whether Eagle can demonstrate by clear and convincing evidence that each of the Asserted Claims is invalid for lack of written description.

162. Whether there is adequate written description support in the specification of the '526 patent for the composition recited in claim 1 that is stored

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at 2-8°C for at least four weeks and that exhibits “less than 1% degradation after storage at 2-8° C. for about four weeks” where, for example:

- Column 41, lines 22 through 37 explicitly recites all of the limitations of claim 1 except the pH of the formulation;
- The specification identifies numerous vasopressin formulations at pH 3.8 and highlights the improved stability results that a vasopressin formulation at pH 3.8 provides;
- Figure 17 shows that the vasopressin formulation at pH 3.8 had less than 1% degradation at 25°C after 4 weeks; and
- The specification reports increased degradation and impurities in vasopressin formulations stored at 25°C compared with those stored at 5°C.

163. Whether there is adequate written description support in the specification of the '526 patent for the full scope of the claimed compositions where, for example:

- Column 41, lines 22 through 37 explicitly recites all of the limitations of claim 1 except the pH of the formulation;
- The specification identifies numerous vasopressin formulations at pH 3.8 and highlights the improved stability results that a vasopressin formulation at pH 3.8 provides;
- Figure 17 shows that the vasopressin formulation at pH 3.8 had less than 1% degradation at 25°C after 4 weeks;
- Vasopressin formulations with acetate buffer necessarily comprise acetic acid;
- The specification teaches that the inventors were in possession of a vasopressin formulation prepared without the use of a buffer, that a vasopressin formulation without a buffer had “stability comparable” to vasopressin formulations prepared with a buffer, and that the

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concentration of acetate buffer would not significantly impact the degradation of vasopressin; and

- The specification reports increased degradation and impurities in vasopressin formulations stored at 25°C compared with those stored at 5°C.

164. Whether there is adequate written description support in the specification of the '209 and '785 patents for the full scope of the claimed compositions where, for example:

- The specification reports 15 months of stability data for vasopressin formulations in which the pH was measured within the claimed range and the impurity levels fell within the claimed values;
- The specification identifies numerous vasopressin formulations at pH 3.7-3.9 and highlights the improved stability results that vasopressin formulations at pH 3.7-3.9 provide;
- Although the Asserted Claims do not require the presence or absence of a buffer, a POSA would have understood that it would be preferable to have a buffer to maintain the claimed pH range; and
- The specification teaches that the inventors were in possession of a vasopressin formulation prepared without the use of a buffer, that a vasopressin formulation without a buffer had “stability comparable” to vasopressin formulations prepared with a buffer, and that the concentration of acetate buffer would not significantly impact the degradation of vasopressin.

165. Whether there is adequate written description support in the specification of the '209 and '785 patents for the claimed composition with “0.1%” SEQ ID NO.: 3 as recited in claim 3 of the '209 patent and claim 4 of the '785 patent where, for example:

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- The specification reports 15 months of stability data for vasopressin formulations in which the pH was measured within the claimed range and the impurity levels fell within the claimed values.

2. Lack of Enablement

166. Whether Eagle can demonstrate by clear and convincing evidence that each of the Asserted Claims is invalid for lack of enablement.

167. Whether Eagle's experts acknowledge that a POSA could have made and used the claimed formulations of the Asserted Patents without undue experimentation.

168. Whether there is adequate enablement support in the specification of the '526 patent for the full scope of the claimed vasopressin formulations where, for example:

- Column 41, lines 22 through 37 explicitly recites all of the limitations of claim 1 except the pH of the formulation;
- The specification identifies numerous formulations at pH 3.8 and highlights the improved stability results that a vasopressin formulation at pH 3.8 provides;
- Figure 17 shows that the formulation at pH 3.8 had less than 1% degradation at 25°C after 4 weeks;
- Vasopressin formulations with acetate buffer necessarily comprise acetic acid;
- The specification teaches that the inventors were in possession of a vasopressin formulation prepared without the use of a buffer, that a vasopressin formulation without a buffer had "stability comparable" to vasopressin formulations prepared with a buffer, and that the concentration of acetate buffer would not significantly impact the degradation of vasopressin;

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- The specification reports increased degradation and impurities in samples stored at 25°C compared with those at 5°C;
- Vasopressin API with less than 1% total impurities was commercially available;
- A POSA could have made the claimed formulations using routine experimentation; and
- A POSA could have tested the claimed formulations to determine which of the formulations satisfied the claim limitations, for example by conducting stability studies, using routine experimentation.

169. Whether there is adequate enablement support in the specification of the '209 and '785 patents for the full scope of the claimed vasopressin formulations where, for example:

- The specification reports 15 months of stability data for vasopressin formulations in which the pH was measured within the claimed range and the impurity levels fell within the claimed values;
- The specification identifies numerous vasopressin formulations at pH 3.7-3.9 and highlights the improved stability results that vasopressin formulations at pH 3.7-3.9 provide;
- Although the Asserted Claims do not require the presence or absence of a buffer, a POSA would have understood that it would be preferable to have a buffer to maintain the claimed pH range;
- The specification teaches that the inventors were in possession of a vasopressin formulation prepared without the use of a buffer, that a vasopressin formulation without a buffer had “stability comparable” to vasopressin formulations prepared with a buffer, and that the concentration of acetate buffer would not significantly impact the degradation of vasopressin.
- A POSA would have known to use vasopressin API that had fewer impurities than the upper limit claimed;

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- Vasopressin API with less than 1 % total impurities was commercially available;
- A POSA could have made the claimed formulations using routine experimentation;
- A POSA could have tested the claimed formulations to determine which of the formulations satisfied the claim limitations, for example by conducting stability studies, using routine experimentation;
- A POSA would have known to use the data for identified impurities with the claimed sequence homology and the data for total impurities to determine the upper and lower limits of the amounts of unidentified impurities with the claimed sequence homology;
- The characterization of unidentified impurities would have been a matter of routine experimentation for a POSA;
- It would have been routine for a POSA to compare the structure of the impurity to SEQ ID. NO. 1 to determine whether it had the claimed sequence homology; and
- It would have been a matter of simple arithmetic for a POSA to determine whether the aggregate amount of impurities with the claimed sequence homology fell within the claimed values.

3. Indefiniteness

170. Whether Eagle can demonstrate by clear and convincing evidence that each of the Asserted Claims is invalid for indefiniteness.

171. Whether claim 13 of the '526 patent, read in light of the specification and prosecution history, informs a POSA with reasonable certainty about the scope of the degradation limitation where, for example:

- A POSA would have understood from the structure of the claims that the start time for the degradation measurement would be when the “storing” of the pharmaceutical formulation began and the end time

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would be “about 4 weeks” after the vasopressin formulation was placed into storage;

- A POSA would have understood that the term “% degradation” means the loss of the vasopressin API as measured by the vasopressin assay; and
- The specification reports assay results of the “degradation of vasopressin” only in terms of percent of label claim.

172. Whether claim 13 of the ’526 patent, read in light of the specification and prosecution history, informs a POSA with reasonable certainty about when to measure pH where, for example:

- Claim 1 of the ’526 patent states: “(a) providing a pharmaceutical composition for intravenous administration . . . wherein the pharmaceutical composition has a pH of 3.8”;
- A POSA would have understood, from reading the plain language of the claims, that the pH is to be measured at the time of the “providing” of the pharmaceutical formulation;
- A POSA would have known how to determine whether the pH limitation was met, for example by conducting a stability study on the formulation in question; and
- The results from such a stability study would have indicated the pH of the formulation over its shelf life and therefore whether and when the formulation would satisfy the claimed pH value.

173. Whether the Asserted Claims of the ’209 patent, read in light of the specification and prosecution history, inform a POSA with reasonable certainty about when to measure pH where, for example:

- Claim 1 of the ’209 patent provides: “A method of increasing blood pressure in a human in need thereof, the method comprising

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administering to the human a unit dosage form . . . wherein: the unit dosage form has a pH of 3.7-3.9”;

- A POSA would have understood, from reading the plain language of the claims, that the pH of the vasopressin formulation is to be measured at any time the unit dosage form can be administered to the human being in need;
- A POSA would have known how to determine whether the pH limitation was met, for example by conducting a stability study on the formulation in question; and
- The results from such a stability study would have indicated the pH of the formulation over its shelf life and therefore whether and when the formulation would satisfy the claimed pH values.

174. Whether the Asserted Claims of the ’785 patent, read in light of the specification and prosecution history, inform a POSA with reasonable certainty about when to measure pH where, for example:

- Claim 1 of the ’785 patent provides: “A pharmaceutical composition . . . wherein the unit dosage form has a pH of 3.7-3.9”;
- A POSA would have understood, from reading the plain language of the claims, that the pH of the vasopressin formulation is to be measured at any time in the formulation’s shelf life;
- A POSA would have known how to determine whether the pH limitation was met, for example by conducting a stability study on the formulation in question; and
- The results from such a stability study would have indicated the pH of the formulation over its shelf life and therefore whether and when the formulation would satisfy the claimed pH values.

VI. ENFORCEABILITY

175. Whether Eagle can demonstrate by clear and convincing evidence that any of the Asserted Patents is unenforceable.

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A. Asserted Patents

176. The Asserted Patents are part of a family of patents arising from U.S. Patent Application 14/610,499 (the “’499 application”). The ’478 and ’239 patents are each a continuation of the ’499 application. The ’526 patent is a continuation-in-part (“CIP”) of the ’239 patent. As such, the ’526 patent contains additional matter in the specification as compared to the ’239 patent. For example, the specification of the ’526 patent contains more than sixty columns of additional disclosure, eight additional figures, and seven additional examples as compared to the ’239 patent. The ’209 and ’785 patents are each a CIP of the ’526 patent. The ’209 and ’785 patents share a common specification with each other, and contain additional matter as compared to the ’526 patent. For example, the specification of the ’209 and ’785 patents contains 15-month stability data for certain vasopressin formulations.

B. pH Declarations

1. August 11, 2015 Vandse Declaration

177. Inventor Sunil Vandse submitted a declaration signed on August 11, 2015 to the PTO under 37 C.F.R. § 1.132 during prosecution of the ’478 patent.

178. The August 11, 2015 Vandse declaration contained the results of experiments performed by the inventors “[t]o analyze the amount of vasopressin

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and associated impurities that were present in the Vasopressin Formulations” adjusted to pH 3.5 to 4.5 with 10 mM acetate buffer.

179. The August 11, 2015 Vandse declaration reported that “[a]t 25 °C, the remaining vasopressin after four weeks was highest between pH 3.6 and pH 3.8 (FIGURE 1). Within the range of pH 3.6 to pH 3.8, the level of impurities was lowest at pH 3.8 (FIGURE 2).”

180. The August 11, 2015 Vandse declaration reported that “[a]t 40 °C, the remaining vasopressin after four weeks was highest between pH 3.6 and pH 3.8 (FIGURE 1). Within the range of pH 3.6 to pH 3.8, the level of impurities was lowest at pH 3.8 (FIGURE 2).”

181. The August 11, 2015 Vandse declaration concluded that “pH 3.8 provided the best overall results because pH 3.8 provided excellent stability, and lower levels of impurities compared to the results at pH 3.6 or pH 3.7.”

2. January 22, 2016 Vandse Declaration

182. Inventor Sunil Vandse submitted a declaration signed on January 22, 2016 to the PTO under 37 C.F.R. § 1.132 during prosecution of the ’478 patent.

183. The January 22, 2016 Vandse declaration was submitted in response to the examiner’s rejection in an Office Action dated October 22, 2015, which stated “Applicant has not provided data for pH values below 3.5 even though the prior art teaches a range of 2.5-4.5.”

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184. The January 22, 2016 Vandse declaration contained the results of experiments performed by the inventors to analyze by HPLC “[t]he amount of vasopressin and associated impurities that were present in” vasopressin formulations adjusted to pH 2.5 to 3.4 with 10 mM acetate buffer.

185. The January 22, 2016 Vandse declaration also contained the results of the experiments reported in the August 11, 2015 Vandse declaration for vasopressin formulations adjusted to pH 3.5-4.5.

186. The January 22, 2016 Vandse declaration reported that “[a]t 25 °C, the percent decrease in vasopressin after four weeks was lowest between pH 3.6 and pH 3.8 (FIGURE 1). Within the range of pH 3.6 to pH 3.8, the level of impurities was lowest at pH 3.8 (FIGURE 2).”

187. The January 22, 2016 Vandse declaration reported that “[a]t 40 °C, the percent decrease in vasopressin after four weeks was lowest between pH 3.6 and pH 3.8 (FIGURE 1). Within the range of pH 3.6 to pH 3.8, the level of impurities was lowest at pH 3.8 (FIGURE 2).”

188. The January 22, 2016 Vandse declaration concluded that “pH 3.8 provided the best overall results because pH 3.8 provided excellent stability, and lower levels of impurities compared to the results at pH 3.6 or pH 3.7.”

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189. The January 22, 2016 Vandse declaration reported, in its two appendices, starting and ending assay and impurity values for vasopressin formulations adjusted to pH 2.5 to 4.5 with 10 mM acetate buffer.

3. March 31, 2016 Kannan Declaration

190. Inventor Vinayagam Kannan submitted a declaration signed on March 31, 2016 to the PTO under 37 C.F.R. § 1.132 during prosecution of the '478 patent.

191. In the March 31, 2016 Kannan declaration, Vinayagam Kannan “reviewed the procedures for and the results of the stability tests presented in the August 14, 2015 and January 22, 2016 [Vandse] Declarations” and concluded “that the differences in the results of the stability tests for each formulation are attributable to a change in pH.”

192. The March 31, 2016 Kannan declaration presented precision results for the experiments presented in the August 14, 2015 and January 22, 2016 Vandse declarations in the form of intra-assay repeatability and inter-analyst repeatability. Intra-assay repeatability was reported as 0.5% for Chemist 1 and 0.2% for Chemist 2. Inter-analyst repeatability was reported as 0.5%. Both intra-assay repeatability and inter-analyst repeatability were reported to meet the acceptance criteria.

193. The March 31, 2016 Kannan declaration concluded that “pH 3.8 provided the best overall results because pH 3.8 provided excellent stability, and lower levels of impurities compared to the results at pH 3.6 or pH 3.7.”

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194. The March 31, 2016 Kannan declaration noted that “[t]he January 22, 2016 Declaration presented plots directly comparing the % total impurities observed in the Vasopressin 2.5 to 3.4 Formulations with those observed in the Vasopressin 3.5 to 4.5 Formulations.”

195. The March 31, 2016 Kannan declaration noted that “[t]he January 22, 2016 Declaration also contained normalized plots comparing the assay (% label claim; vasopressin remaining) observed in the Vasopressin 2.5 to 3.4 Formulations with those observed in the Vasopressin 3.5 to 4.5 Formulations. The data were normalized and presented as % assay decrease of vasopressin over the four-week study period, rather than absolute assay, because the amount of starting vasopressin varied between the Vasopressin pH 2.5 to 3.4 Formulations and the Vasopressin pH 3.5 to 4.5 Formulations.”

196. The March 31, 2016 Kannan declaration concluded that “the criticality of pH 3.8 in stabilizing a vasopressin formulation would be desirable to the FDA and ICH, and therefore would result in a practical benefit to a user of a vasopressin.”

197. The August 11, 2015 Vandse declaration, January 22, 2016 Vandse Declaration, and March 31, 2016 Kannan declaration were also filed during prosecution of the ’526 patent.

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4. May 1, 2017 Kannan Declaration

198. Inventor Vinayagam Kannan submitted a declaration signed on May 1, 2017 to the PTO under 37 C.F.R. § 1.132 during prosecution of the '526 patent.

199. The May 1, 2017 Kannan declaration concluded that “cooling a vasopressin formulation would not cause an increase in decomposition in comparison to a vasopressin formulation stored at 25 °C or 40 °C. Thus, the stability of the formulations at 5 °C should not be lesser than the stability of the same formulations at 25 °C or 40 °C. The stability data obtained at 25 °C or 40 °C are sufficient to show at least a similar level of stability at the claimed temperatures.”

5. May 22, 2017 Kannan Declaration

200. Inventor Vinayagam Kannan submitted a declaration signed on May 22, 2017 to the PTO under 37 C.F.R. § 1.132 during prosecution of the '239 patent.

201. The May 22, 2017 Kannan declaration referred to the data from experiments reported in the August 11, 2015 Vandse declaration, January 22, 2016 Vandse Declaration, and March 31, 2016 Kannan declaration.

202. The May 22, 2017 Kannan declaration reported that the results of the experiments reported in the August 11, 2015 Vandse declaration, January 22, 2016 Vandse Declaration, and March 31, 2016 Kannan declaration “suggest that the stability of a vasopressin formulation is affected by pH” and concluded that “the

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differences in the results of the stability tests for each formulation are attributable to a change in pH.”

203. The May 22, 2017 Kannan declaration concluded that “[t]he claimed pH range of 3.5 to 4.1 reflects the good stability of vasopressin provided at pH 3.5 to 4.1 at both temperatures tested.”

204. The May 22, 2017 Kannan declaration presented precision results for the experiments presented in the August 14, 2015 and January 22, 2016 Vandse declarations in the form of intra-assay repeatability and inter-analyst repeatability. Intra-assay repeatability was reported as 0.5% for Chemist 1 and 0.2% for Chemist 2. Inter-analyst repeatability was reported as 0.5%. Both intra-assay repeatability and inter-analyst repeatability were reported to meet the acceptance criteria.

205. The May 22, 2017 Kannan declaration noted that “FIGURES 5-6 provide direct comparisons of the % total impurities observed in the Vasopressin 2.5 to 3.4 Formulations with those observed in the Vasopressin 3.5 to 4.5 Formulations.”

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FIGURE 5

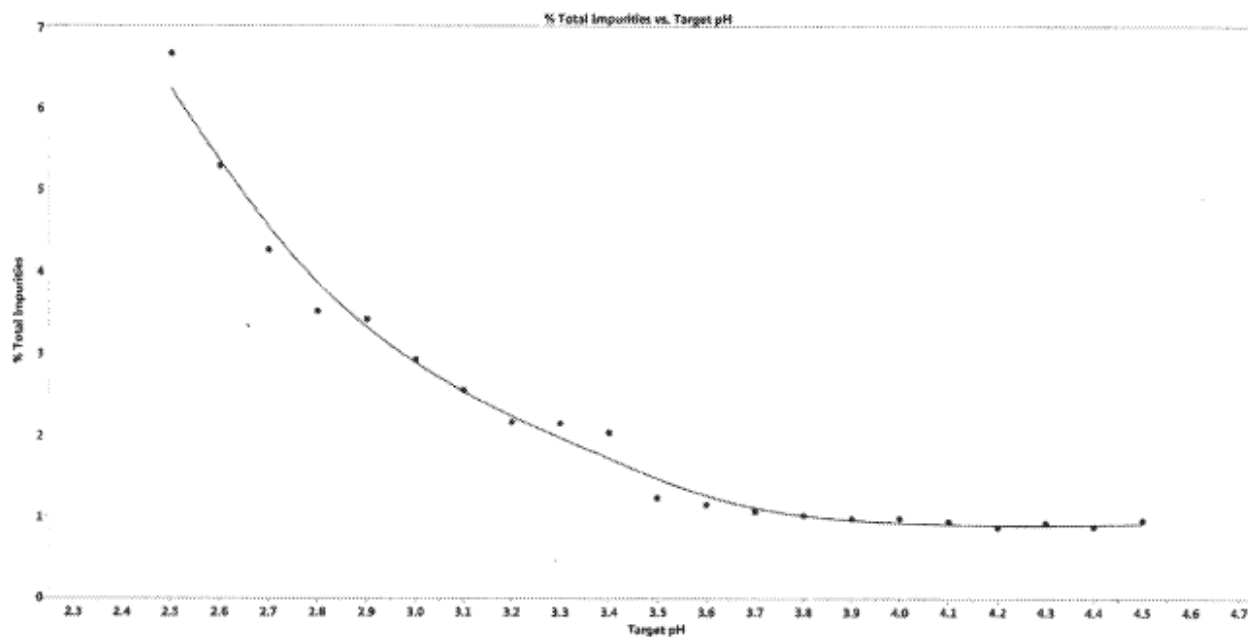
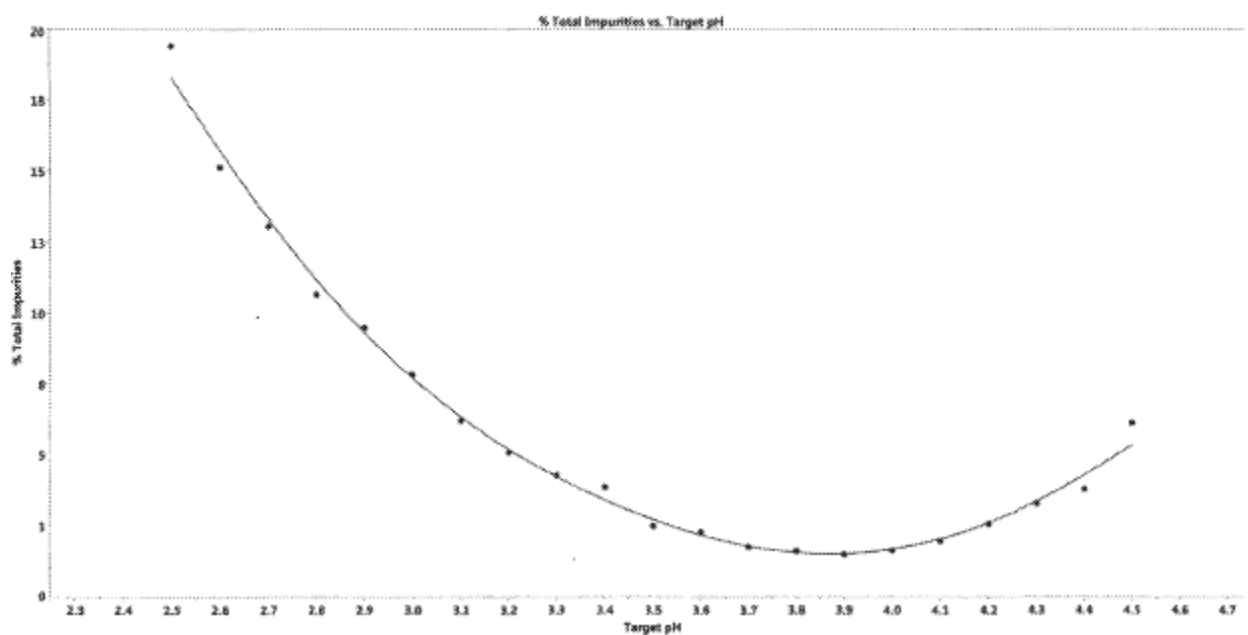


FIGURE 6



206. The May 22, 2017 Kannan declaration noted that “FIGURES 7-8 provide normalized plots comparing the assay (% label claim; vasopressin

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remaining) observed in the Vasopressin 2.5 to 3.4 Formulations with those observed in the Vasopressin 3.5 to 4.5 Formulations. The data were normalized and presented as % assay decrease of vasopressin over the four-week study period, rather than absolute assay, because the amount of starting vasopressin varied between the Vasopressin pH 2.5 to 3.4 Formulations and the Vasopressin pH 3.5 to 4.5 Formulations.”

FIGURE 7

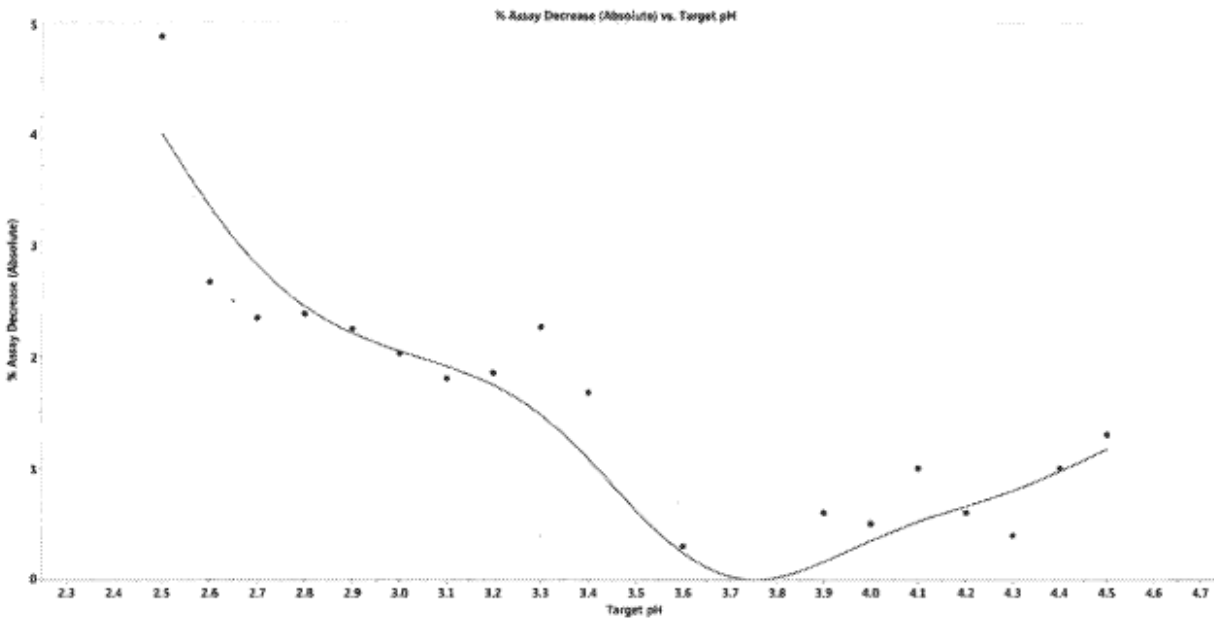
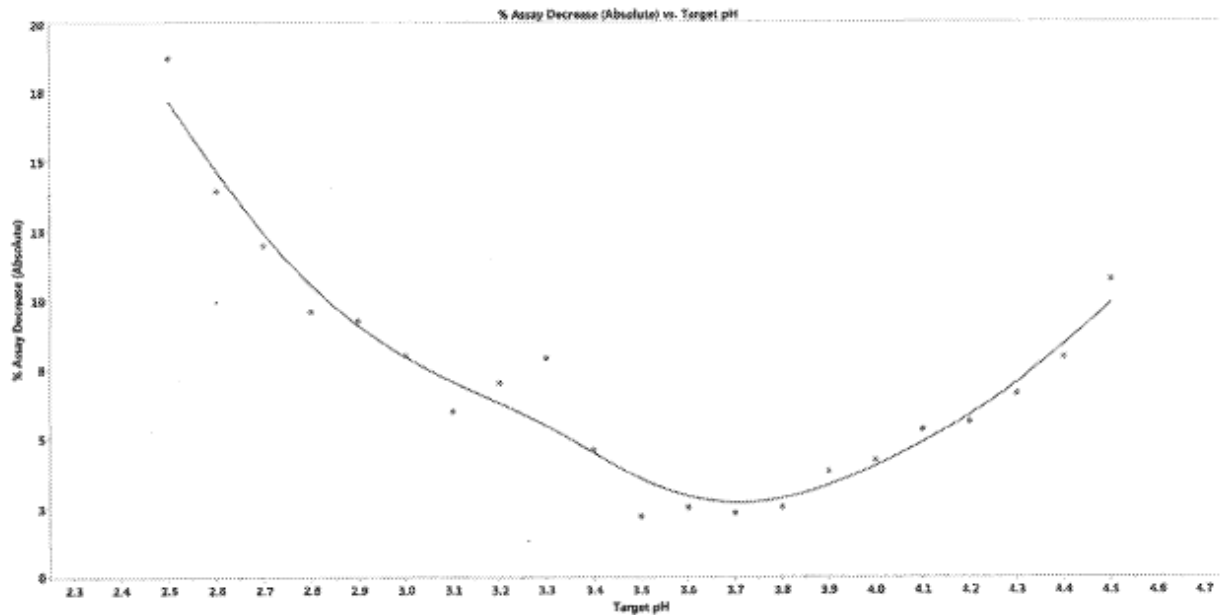


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FIGURE 8



207. The y-axis of the graphs presented in Figure 5 and Figure 6 is “% Total Impurities.”

208. The y-axis of the graphs presented in Figure 7 and Figure 8 is “% Assay Decrease (Absolute).”

209. The experiments reported in the aforementioned Kannan and Vandse declarations used [REDACTED]

C. Declarations related to the April 2014 VASOSTRICT Label

210. Inventor Vinayagam Kannan submitted a declaration signed on November 24, 2015 to the PTO under 37 C.F.R. § 1.130(a) during prosecution of the '239 patent.

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211. The Office Action cited in the November 24, 2015 Kannan declaration alleged that the April 2014 VASOSTRICT Label anticipated the invention recited in the pending claims at issue.

212. The November 24, 2015 Kannan declaration states “Matthew Kenney and I invented the subject matter of the Label that is cited in the Office Action. As part of my responsibilities, I forwarded the details of the joint invention to the regulatory department of PAR STERILE.”

213. As of November 24, 2015, the relevant pending claim of U.S. Application No. 14/717,877 (the application that led to the '239 patent) recited:

16. (New) A method of increasing blood pressure in a human in need thereof, the method comprising:

a) providing a pharmaceutical composition for intravenous administration comprising, in a unit dosage form: i) from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically-acceptable salt thereof; ii) chlorobutanol; iii) acetic acid; and iv) water, wherein the unit dosage form has a pH of 3.4 to 3.6;

b) storing the unit dosage form at 2-8 °C; and

c) administering the unit dosage form to the human;

wherein:

the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute; and

the human is hypotensive.

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214. Dr. Kannan was an inventor of that subject matter, including without limitation the limitation related to storing the composition in refrigerated conditions.

215. Michelle Bonomi-Huvala submitted a declaration signed on November 24, 2015 to the PTO under 37 C.F.R. § 1.130(a) during prosecution of the '239 patent.

216. As of November 24, 2015, Michelle Bonomi-Huvala was “Senior Vice President, Regulatory Affairs at Par Pharmaceutical, Inc.”

217. The November 24, 2015 Bonomi-Huvala declaration states that “[a]s part of the inventors’ employment responsibilities, the inventors forwarded the details of the joint invention to my department. One of the functions performed by my department is the submission of regulatory filings to the FDA. Upon receiving the details of the joint invention and at my direction, a member of my department submitted the details of the joint invention to the FDA in the filings directed toward regulatory approval of the VASOSTRICT product manufactured by PAR CO.”

218. The November 24, 2015 Bonomi-Huvala declaration further states that “[t]he FDA obtained the subject matter disclosed in the Label directly from a member of my department, who obtained the subject matter directly from the

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inventors. Thus, the FDA obtained the subject matter recited in the Label from the inventors.”

219. [REDACTED]

[REDACTED]

[REDACTED] In

particular, Dr. Kannan [REDACTED]

[REDACTED] and was a named inventor with respect to the then-pending claims of the Application No. 14/717,877. [REDACTED]

[REDACTED]

[REDACTED] This and other information compiled by [REDACTED] was incorporated into the proposed label submitted to the FDA by the regulatory department and that was ultimately published by the FDA as the April 2014 VASOSTRICT Label. Thus, the proposed label submitted to the FDA by the regulatory department at Par was obtained, directly or indirectly, from Kannan, one of the joint inventors.

D. Alleged Inequitable Conduct

220. Whether Eagle can demonstrate by clear and convincing evidence that Vinayagam Kannan, Matthew Kenney, Michelle Bonomi-Huvala, or Craig Kenesky knowingly submitted unmistakably false declarations to the PTO during

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prosecution of the '239 patent, and whether they specifically intended to deceive the PTO by submitting such declarations.

221. Whether Eagle can demonstrate by clear and convincing evidence that the April 2014 VASOSTRICT Label was material to the patentability of the non-asserted '239 patent. The above sections relating to invalidity of the Asserted Patents are relevant to this issue.

222. Whether Eagle can demonstrate by clear and convincing evidence that the April 2014 VASOSTRICT Label disclosed the "0-2% vasopressin degradation products" limitation of the '239 patent.

223. Whether, even if there is a finding of inequitable conduct with respect to the '239 patent, Eagle can demonstrate by clear and convincing evidence that such conduct would infect the prosecution of the Asserted Patents.

224. Whether Eagle can demonstrate by clear and convincing evidence that the April 2014 VASOSTRICT Label was material to the patentability of the Asserted Patents. The above sections relating to invalidity of the Asserted Patents are relevant to this issue.

225. Whether Eagle can demonstrate by clear and convincing evidence that the inventors of the Asserted Patents knowingly withheld material information from the PTO during prosecution of the Asserted Patents.

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226. Whether any information allegedly not disclosed during prosecution, including alleged prior art, internal testing data, and other information, were material to the prosecution of the Asserted Patents.

227. Whether Eagle can demonstrate by clear and convincing evidence that the allegedly withheld information about PITRESSIN was material to the patentability of the Asserted Claims. The above sections relating to invalidity of the Asserted Patents are relevant to this issue.

228. Whether Eagle can demonstrate by clear and convincing evidence that the inventors had knowledge of the relevant properties of PITRESSIN during prosecution of the Asserted Patents.

229. Whether any material information was withheld from the PTO, and whether any of the above-named actors acted with the specific intent to deceive the PTO.

230. Whether any information not disclosed to the PTO was either cumulative or was not disclosed for scientific reasons.

1. Par did not commit inequitable conduct during prosecution of the '239 patent.

231. Eagle asserts that Vinayagam Kannan and Michelle Bonomi-Huvala submitted false declarations to the PTO to remove the April 2014 VASOSTRICT Label from consideration as prior art and to secure issuance of the '239 patent.

The declarations are not unmistakably false and, even if proven false by clear and

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convincing evidence, Eagle cannot prove by clear and convincing evidence that they were submitted with specific intent to deceive the PTO.

232. The November 24, 2015 Kannan Declaration states that “[t]he FDA obtained the subject matter disclosed in the Label directly from the regulatory department of PAR STERILE, who obtained the subject matter directly from the inventors. Thus, the FDA indirectly obtained the subject matter disclosed in the Label from the inventors.” Kannan Decl. ¶ 8. Ms. Bonomi-Huvala’s November 24, 2015 Declaration contains a similar statement. *See* Bonomi-Huvala Decl. ¶¶ 6-7.

233. The November 24, 2015 Kannan Declaration also contains a listing of administration and formulation limitations recited in the Label, for example, “a method of increasing blood pressure in a hypotensive human.” Kannan Decl. ¶ 7. The final two sentences of this paragraph state “The Label recites refrigeration of the diluted vasopressin for up to 24 hours. *Label*, page 1. The FDA obtained this information from me and Matthew Kenney, as we invented this subject matter.” *Id.*

234. In his deposition, Dr. Kannan stated that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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235. It is unreasonable to assume that Dr. Kannan or Craig Kenesky intended to represent to the PTO that either Dr. Kannan or Mr. Kenney, both pharmaceutical formulators, invented vasopressin, a method of increasing blood pressure using vasopressin, an administration regime for vasopressin, or an infusion rate for vasopressin. As the examiner was well-aware, such elements from the Label were known in the prior art to a POSA at the time of Dr. Kannan's November 24, 2015 declaration.

236. Moreover, in addition to his contributions described above, Dr. Kannan [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

237. The representations in the November 24, 2015 declarations are thus not unmistakably false, because [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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238. The witnesses' and Par's lack of current knowledge regarding the preparation of the April 2014 VASOSTRICT Label and forwarding of the details of the invention does not create a presumption that the November 24, 2015 declarations are unmistakably false.

239. For example, Ms. Bonomi-Huvala stated numerous times at her deposition that [REDACTED]

[REDACTED]

[REDACTED]

240. Neither Vinayagam Kannan, Matthew Kenney, Michelle Bonomi-Huvala, nor Craig Kenesky engaged in affirmatively egregious misconduct in connection with the November 24, 2015 declarations.

241. The April 2014 VASOSTRICT Label was cited as an anticipating reference in an Office Action dated October 21, 2015 during prosecution of the '239 patent. The anticipation rejection was based on the Label's pH disclosure, which was the pH range recited in the pending claims at the time. However, the pH limitation in the claims was later amended to recite a range of 3.5-4.1 and degradation-related limitations were added to the claims.

2. The alleged inequitable conduct during prosecution of the '239 patent, even if proven, would not infect the Asserted Patents.

242. Eagle asserts that any alleged inequitable conduct during prosecution of the '239 patent, if proven by clear and convincing evidence, would render the

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Asserted Patents unenforceable under the doctrine of infectious unenforceability. However, at least because there is no immediate and necessary relation between this alleged conduct and the prosecution of the Asserted Patents, the Asserted Patents cannot be found unenforceable under this doctrine.

243. Neither Vinayagam Kannan, Michelle Bonomi-Huvala, nor Craig Kenesky engaged in inequitable conduct during prosecution of the '239 patent. However, a finding of inequitable conduct against the '239 patent does not and would not infect the Asserted Patents.

244. Eagle asserts that the inventors would not have been able to show the criticality of the claimed pH values over the pH range disclosed in the April 2014 VASOSTRICT Label. However, the pH range in the label does not raise a presumption of obviousness for the claimed pH values. Accordingly, the inventors would not have had to demonstrate criticality over the pH range disclosed in the April 2014 VASOSTRICT Label.

245. PPC, the primary reference relied on by Examiner Bradley in initially rejecting the claims of each of the Asserted Patents, disclosed a pH range of 2.5-4.5. This range contains pH range disclosed in the April 2014 VASOSTRICT Label. Therefore, the pH range of the April 2014 VASOSTRICT Label is cumulative of the 2.5-4.5 range of PPC.

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246. Therefore, Eagle cannot demonstrate by clear and convincing evidence that the April 2014 VASOSTRICT Label is but-for material to the prosecution of any of the Asserted Patents. Further, any alleged misconduct during prosecution of the '239 patent, if proven by clear and convincing evidence, does not infect the Asserted Patents.

3. The inventors did not withhold material information during prosecution of the Asserted Patents.

- a) *The allegedly withheld information about PITRESSIN is not but-for material.*

247. Eagle asserts that Par committed inequitable conduct by intentionally withholding information regarding a prior art PITRESSIN formulation with the specific intent to deceive the PTO, but Eagle cannot prove by clear and convincing evidence that this information is but-for material, nor that it was withheld with specific intent to deceive the PTO.

248. Eagle cannot meet its burden of proving by clear and convincing evidence that any prior art sale or use of PITRESSIN anticipated or rendered obvious any Asserted Claim.

249. PPC, the primary reference relied on by Examiner Bradley in initially rejecting the claims of each of the Asserted Patents, disclosed a pH range of 2.5-4.5. [REDACTED]

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[REDACTED]

[REDACTED]

250. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

251. Therefore, Eagle cannot prove by clear and convincing evidence that the information allegedly withheld regarding PITRESSIN is but-for material to the prosecution of any of the Asserted Patents.

252. Additionally, Eagle cannot demonstrate by clear and convincing evidence that the inventors had knowledge of the relevant properties of PITRESSIN, including the pH values of particular batches thereof, during prosecution of the Asserted Patents.

b) [REDACTED]
is not but-for material.

253. Eagle asserts that Par committed inequitable conduct by intentionally withholding [REDACTED] with the specific intent to deceive the PTO, but Eagle cannot prove by clear and convincing evidence that this data is but-for material, nor that it was withheld with specific intent to deceive the PTO.

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254. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

255. [REDACTED]

[REDACTED] The inventors reported normalized assay data because of “the difference in starting amounts” of vasopressin between the two sets of experiments. *See, e.g.*, March 31, 2016 Kannan Declaration, ¶ 15. Thus, the inventors presented a normalized comparison of assay data in the pH declarations.

256. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

257. The inventors clearly disclosed this difference to the PTO. *Compare* March 31, 2016 Kannan Declaration, ¶ 13 (“The January 22, 2016 Declaration presented plots *directly comparing the % total impurities* observed in the Vasopressin 2.5 to 3.4 Formulations with those observed in the Vasopressin 3.5 to 4.5 Formulations.”) *with id.*, ¶ 13 (“The January 22, 2016 Declaration also contained *normalized plots comparing the assay* (% label claim; vasopressin

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remaining) observed in the Vasopressin 2.5 to 3.4 Formulations with those observed in the Vasopressin 3.5 to 4.5 Formulations.”) (emphases added).

258. The inventors reasonably presented normalized assay data and non-normalized impurity data, and [REDACTED] [REDACTED] based on their scientific judgment regarding the proper way to present the data and without any intent to deceive the PTO. [REDACTED] [REDACTED] [REDACTED]

c) *The other allegedly withheld information identified by Eagle is not but-for material.*

259. Eagle asserts that Par committed inequitable conduct by intentionally withholding [REDACTED] [REDACTED] with the specific intent to deceive the PTO. However, Eagle cannot prove by clear and convincing evidence that this information is but-for material, nor that it was withheld with specific intent to deceive the PTO.

260. Further, Eagle cannot prove by clear and convincing evidence that Par withheld information concerning variability in Par’s testing method, because Par’s data concerning variability used to validate its testing method was provided to the Examiner. For example, the March 31, 2016 Kannan declaration discloses the inherent variability of the testing method, stating that “[t]he intra-assay

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repeatability met the acceptance criteria ($\% \text{ RSD} \leq 2.0\%$) with values of 0.5% and 0.2%.”

261. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

262. [REDACTED]

[REDACTED]

[REDACTED]

263. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

264. Further, the inventors disclosed both the differences in impurity levels between different pH values and the inherent variability of the testing method.

265. For example, the appendices to the January 22, 2016 Vandse declaration disclose all of the starting and ending impurity and assay values for all tests conducted and reported in the pH declarations.

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266. Thus, this information was not withheld from the PTO, and certainly not with the specific intent to deceive the PTO. Even if it were allegedly withheld, it would not be but-for material to the patentability of the Asserted Patents and would not affect the determination that the claimed pH ranges are critical to the claimed inventions.

VII. EXCEPTIONAL CASE

267. As an initial matter, exceptional case is not an issue to be tried, but rather an issue for the Court to decide post-trial.

268. Eagle's statement appears to identify three issues of fact related to exceptional case all of which Par denies: (1) whether Par had no reasonable basis to bring and maintain this lawsuit, (2) whether Par brought this suit in bad faith, and (3) whether Eagle's allegations of inequitable conduct demonstrate that this case is exceptional. While Par responds to some of the more specific facts raised by Eagle below, any fact alleged by Eagle not specifically responded to should not be considered an admission by Par.

A. Eagle Infringes the Asserted Patents and Par is Entitled to Enforce Its Patent Rights

269. Eagle's allegations that Par lacked a reasonable basis to bring and maintain this lawsuit are meritless.

270. The Asserted Patents were issued by the Patent Office and presumed valid.

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271. Prior to filing its Complaint against Eagle, Eagle provided a heavily redacted version of its ANDA.

272. Since the Asserted Patents cover a Vasopressin Injection product for the duration of its shelf-life, Par asked Eagle to provide a complete and unredacted version of its ANDA. Eagle refused to do so.

273. Accordingly, Par brought suit asserting infringement of the Asserted Patents based on the limited information made available at that time.

274. Eagle's obfuscation continued into discovery. For example, by the time Par submitted initial contentions, Eagle continued to refuse to provide all stability data generated by or for Eagle and all communications with the FDA regarding Eagle's ANDA.

275. Nonetheless, the information made available to Par at the time initial contentions were served supported Par's infringement theory. Namely, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

276. As discovery progressed, Eagle continued to avoid its discovery obligations by withholding evidence of infringement despite repeated inquiries by counsel for Par. By way of example, Par repeatedly asked Eagle to produce [REDACTED]

[REDACTED]

EXHIBIT 2

[REDACTED]

[REDACTED]

[REDACTED]

277. Par's receipt of complete stability data from Eagle along with all communications with the FDA regarding Eagle's ANDA confirmed Eagle's infringement. In short, Eagle submitted stability data demonstrating its infringement as set forth elsewhere in this Pretrial Order.

278. With respect to Eagle's allegations of an exceptional case based on Par's assertion of the '239 patent, much of those allegations are premised on Eagle's claim of inequitable conduct, which Par disputes for the reasons set forth above. Par's decision to drop the '239 patent during fact discovery, undercuts Eagle's allegations that Par's litigation conduct was exceptional.

279. Similarly, Eagle's allegations of an exceptional case based on Par's assertion of the "buffer patents," is misplaced. Par's decision to streamline the case and narrow the disputed issues for the Court, notwithstanding its good faith basis to continue to assert those patents, is what courts encourage litigants to do, and is not in any way evidence of any improper conduct.

280. Finally, Par objects to Eagle's late addition of its incomplete and inaccurate allegations regarding supplemental expert reports that were served in this case. Eagle completely ignores that the supplemental reports were prompted

EXHIBIT 2

by Eagle producing new stability data and its own supplemental expert reports relying on such data. Par's decision to further streamline the case to avoid a cascade of even further supplemental expert reports reduced the burden and expense on all of the Parties on the eve of trial, and does not evidence that Par lacked a reasonable basis to maintain its lawsuit against Eagle.

B. Eagle's Allegations of Bad Faith are Irrelevant and Improper


281. Eagle's allegations of bad faith are largely a repeat of Eagle's non-infringement and inequitable conduct allegations, with added focus on Par's pricing of its VASOSTRICT products since the FDA approved Par's NDA. Those allegations are irrelevant to any disputed issue in this case, and are a thinly veiled attempt to discredit Par in the eyes of the Court and to distract from the relevant issues of liability which strongly favor Par. Par further objects to Eagle's late addition of allegations regarding the FDA's Unapproved Drugs Initiative for the same reasons.

C. Eagle's Allegations of Inequitable Conduct Lack Merit

282. Eagle further incorporates its allegations of inequitable conduct to support its exceptional case allegations. Par disputes these allegations for the same reasons set forth above with respect to Eagle's inequitable conduct allegations.

EXHIBIT 3

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

PAR PHARMACEUTICAL, INC.,)	
PAR STERILE PRODUCTS, LLC, and)	
ENDO PAR INNOVATION)	
COMPANY, LLC,)	
)	C.A. No. 18-823-CFC
Plaintiffs,)	
)	
v.)	
)	
EAGLE PHARMACEUTICALS INC.,)	
)	
Defendant.)	

DEFENDANT'S STATEMENT OF ISSUES OF FACT
THAT REMAIN TO BE LITIGATED

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Pursuant to Local Rule 16.3(c)(4) and the Court’s Scheduling Order (D.I. 120, 148), Defendant Eagle Pharmaceuticals Inc. (“Eagle” or “Defendant”) submits this Statement of Issues of Fact that Remain to be Litigated (“Statement”). Eagle incorporates by reference any issues of fact set forth in its responsive papers to any comparable material filed or submitted by Plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC (collectively, “Par” or “Plaintiffs”).

In this action, Plaintiffs are currently asserting U.S. Patent No. 9,687,526 (“the ’526 patent”); U.S. Patent No. 9,744,209 (“the ’209 patent”); and U.S. Patent No. 9,750,785 (“the ’785 patent”) (collectively, the “Patents-in-Suit”).¹ Specifically, Plaintiffs are asserting claim 13 of the ’526 patent; claims 1, 3–5, and 7 of the ’209 patent; and claims 1, 4, 5, and 8 of the ’785 patent (the “Asserted Claims”).

Eagle reserves all rights with respect to these disclosures, including the right to amend, supplement, or otherwise modify these disclosures without prejudice according to the schedule set forth by the Parties for pre-trial exchanges, the local rules, the Federal Rules of Civil Procedure, and any other basis in fact or law. Eagle

¹ The Patents-in-Suit share two common inventors and a common chain of priority to U.S. Patent No. 9,744,239 (“the ’239 patent”), and therefore may be referred to as the “’239 family.” Each of these patents also claims priority to U.S. Application 14/610,499. Par has not disputed that the Patents-in-Suit are not entitled to priority dates earlier than their own filing dates, based on their claims of priority to the ’239 patent and ’499 application.

reserves the right to affirmatively use, elaborate upon, or dispute any fact cited by Plaintiffs, including the scientific bases for such fact or Plaintiffs' application of such fact in this case.

By including a fact herein, Eagle does not assume the burden of proof or production with regard to that fact. For instance, Plaintiffs bear the burden of proof with respect to infringement. As such, Eagle reserves the right to object to and/or contest those alleged facts and present any and all rebuttal evidence in response to those alleged facts when identified by Plaintiffs. Any fact not specifically admitted in the parties' Statement of Uncontested Facts should be considered contested, even if not specifically enumerated herein.

To the extent Eagle's Statement of Issues of Law that Remain to be Litigated contains issues of fact, those issues are incorporated herein by reference. If the Court determines that any issue identified in this list as an issue of fact is more properly considered an issue of law, Eagle incorporates such issue by reference into its Statement of Issues of Law. Eagle incorporates by reference its expert reports in support of any proof to be presented by expert testimony. To the extent that a fact or an issue of fact in one section applies to another section, claim or theory, it is incorporated therein as well without separate repetition. Eagle incorporates by reference the Statement of Uncontested Facts.

I. BACKGROUND

A. Overview Of The Case

1. This is a patent infringement action arising under the patent laws of the United States (35 U.S.C. §§ 100 *et seq.*) and the Hatch-Waxman Act (21 U.S.C. § 355) based on Eagle's filing of Abbreviated New Drug Application No. 211538 ("Eagle's ANDA") seeking approval to commercially manufacture, use, offer to sell, and sell in the United States a generic version of Par's original Vasostrict® product as approved by the FDA in April 2014 ("Original Vasostrict®").

2. Each of the Patents-in-Suit is listed in the FDA publication titled "Approved Drugs With Therapeutic Equivalence Evaluations" (the "Orange Book") as covering Vasostrict®. The Orange Book additionally lists U.S. Patent Nos. 9,744,239 (the "'239 patent"), 9,375,478 (the "'478 patent"), and 9,937,223 (the "'223 patent") as covering Vasostrict®.

3. Every claim of the '526, '209, '785, '223 and '478 patents requires vasopressin formulations with a pH value within the range of 3.7–3.9. The '239 patent, in contrast, requires vasopressin formulations with a pH within the broader range of 3.5–4.1. Additionally, the '478 and '223 patents (collectively, the "Buffer Patents") are directed to vasopressin formulations that include an "acetate buffer."

4. On April 16, 2018 and May 18, 2018, Eagle sent Paragraph IV notice letters informing Par that Eagle intended to market its ANDA Product before the

expiration of the '239, '526, '209, '785, '223 and '478 patents, that Eagle's ANDA product and its use upon approval would not infringe any valid, enforceable claim of those patents, and that the claims of those patents are invalid. Among other noninfringement bases, Eagle informed Par that it will not infringe the '526, '209, '785, '223 and '478 patents because [REDACTED]

[REDACTED] whereas each of these patents requires vasopressin formulations with a pH value within the range of 3.7–3.9. Eagle also informed Par that its ANDA Product will not [REDACTED] and therefore will not infringe the Buffer Patents.

5. Nevertheless, on May 31, 2018, Par filed a complaint against Eagle (the "Complaint") asserting infringement of the '239, '526, '209, '785, '478, and '223 patents. On August 6, 2018, Eagle filed its answer to Par's Complaint, asserting counterclaims of noninfringement and invalidity of the '239, '526, '209, '785, '478, and '223 patents.

6. On October 30, 2019, Eagle filed an amended answer and counterclaims to Par's Complaint to add counterclaims of inequitable conduct with respect to the '239, '526, '209, and '785 patents, including based on the filing of false declarations during prosecution of the '239 patent that also tainted the prosecution of the '526, '209, and '785 patents, as discussed further in Section II below.

7. In response to Eagle's inequitable conduct counterclaims, on November 11, 2019, Par moved to dismiss the '239 patent. In the same motion, Par also moved to dismiss the Buffer Patents, after several of its named inventors confirmed at their depositions that the acetic acid in the original Vasostrict® formulation, [REDACTED]

8. On December 20, 2019, the parties stipulated to dismissal of all claims, counterclaims, and defenses related to the '239 patent and the Buffer Patents. With the dismissal of the '239 patent, no patent remains in this action that [REDACTED]

B. Unapproved Vasopressin Products

9. Since the institution of the FDA drug approval process in 1938, manufacturers have been permitted to continue to market drug products that existed before the FDA approval process was instituted, so-called "grandfathered" products. In order to maintain such grandfathered status, the composition and conditions of use on a product's labeling must remain unchanged.

10. Stable vasopressin formulations, under the trade name Pitressin®, were sold as unapproved products for almost a century with the same identified formulation: 20 units/mL or 0.038 mg/mL of vasopressin, [REDACTED] mg/mL of

chlorobutanol, acetic acid for pH adjustment to pH 3.4 to 3.6 (approximately 0.22 mg per mL of solution), and water for injection.

11. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

12. For decades, Pitressin® and other vasopressin products were used to treat hypotension, including vasodilatory and septic shock, as reflected in references such as A. Russell et al., *Vasopressin versus Norepinephrine Infusion in Patients with Septic Shock*, N. Eng. J. Med. 358(9):877-87 (2008) (“Russell 2008”) and standard guidelines such as *Intravenous Medications* (B. L. Gahart & A. R. Nazareno et al., eds. 29th ed. 2013) (“Intravenous Medications 2013”).

13. Pitressin® was sold from at least 1927 until 2014 by Par and its predecessors, including Parke-Davis, King Pharmaceuticals, Parkedale, and finally JHP Pharmaceutical (“JHP”). JHP was acquired by Par Pharmaceutical Inc. in February 2014, after which its name was changed to Par Sterile Products, LLC. Par Sterile Products is one of the Plaintiffs in this action.

14. Pitressin® was labeled with a shelf life of 24 months at room temperature.

15. Although the release and stability specifications for JHP's unapproved Pitressin® were pH 2.5 to 4.5, the in-process pH range for Pitressin® during manufacture was [REDACTED]. The Pitressin® label did not indicate the pH of the formulation.

16. Release testing of JHP's unapproved Pitressin® product demonstrated that some lots were released at a pH between [REDACTED]

17. Stability testing of JHP's unapproved Pitressin® product demonstrated that some lots increased their pH during their shelf lives to a pH between [REDACTED]
[REDACTED]

18. Other unapproved vasopressin products with the same formulation as Pitressin® were sold by companies including Fresenius Kabi, Pharmaceutical Partners of Canada ("PPC"), and Cardinal Health. The labels for these products either did not specify the pH of the product or included only the stability specification range of 2.5 to 4.5.

19. Other companies sold unapproved vasopressin products with slightly different formulations. For example, American Regent (formerly Luitpold Pharmaceuticals) sold an unapproved vasopressin product from at least 1996–2012 comprising the same concentration of vasopressin and chlorobutanol as Pitressin®, but with pH adjustment to [REDACTED], and the addition of sodium chloride.

20. Standards for unapproved vasopressin products were set by the United States Pharmacopeia (USP), with a pH range of 2.5 to 4.5. The World Health Organization (WHO) also provided a standard for an aqueous vasopressin formulation for analysis of vasopressin drug products (“WHO Standard”). That WHO Standard required refrigeration of aqueous vasopressin formulations for maximum stability.

C. JHP’s NDA for Pitressin®

21. In 2006, the FDA issued guidance encouraging companies to file New Drug Applications (“NDAs”) on products that were sold as unapproved products. This guidance was updated on September 19, 2011 to clarify the FDA’s enforcement priorities with respect to unapproved products and their removal from the market.

22. [REDACTED]

[REDACTED]

[REDACTED]

23. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

24. [REDACTED]

[REDACTED]

[REDACTED].

25. On September 25, 2012, JHP filed its NDA No. 204485 for its Pitressin® product. The proposed formulation was identical to that of its prior unapproved formulation [REDACTED]

26. JHP did not conduct any clinical studies to support its NDA, instead relying on the published literature, such as Russell 2008, standard reference guides, and known treatment algorithms to show the effectiveness of Pitressin® in treating hypotension, including in vasodilatory and septic shock.

27. [REDACTED]

[REDACTED]

28. [REDACTED]

[REDACTED]

[REDACTED]

D. Par's Original Vasostrict® Product

29. The FDA approved JHP's NDA No. 204485 for Pitressin®, renamed "Vasostrict®," on April 17, 2014 ("Original Vasostrict®")

30. The formulation of Original Vasostrict® was identical to that of unapproved Pitressin® without [REDACTED]

comprising 20 units/mL or 0.0377 mg/mL vasopressin, 0.5% or ■ mg chlorobutanol, acetic acid for pH adjustment to 3.4 to 3.6, and water for injection.

31. At the same time, the FDA approved the prescribing information for original Vasostrict® (“April 2014 Vasostrict® Label”). That label identified the formulation of Original Vasostrict®, including its manufacture pH of 3.4–3.6. The label also included the indications as well as dosage and administration instructions for treatment of hypotension, including vasodilatory shock, post-cardiotomy shock and septic shock.

32. Soon after the initial approval of Original Vasostrict®, in September 2014, the FDA approved new prescribing information, adding a refrigerated storage instruction (“Store between 2°C and 8°C (36°F and 46°F). Do not freeze.”) (“September 2014 Vasostrict® Label”).

33. Original Vasostrict® was first sold by Par in November 2014 with the September 2014 Original Vasostrict® Label.

34. In May 2015, the FDA approved new prescribing information for Original Vasostrict®, which permitted storage of the product for up to twelve months at room temperature or 24 months refrigerated (“March 2015 Vasostrict® Label”).

35. Original Vasostrict® was sold with the March 2015 Vasostrict® Label from May 2015.

36. Although the target pH for Original Vasopressin® was 3.4–3.6, it had a release pH specification of [REDACTED], and a shelf life stability specification of [REDACTED].

37. Original Vasopressin® was indicated for the treatment of hypotension, including vasodilatory shock from post-cardiotomy shock and septic shock. Original Vasopressin®'s prescribing information contained instructions for intravenous administration at a dose between 0.01 and 0.07 units/minute to treat hypotension including vasodilatory shock from post-cardiotomy shock and septic shock.

38. The FDA removed other vasopressin products from the market in December 2014, following the initial approval and commercial launch of Original Vasopressin®. At that time, Original Vasopressin® became the only vasopressin product available in the United States.

39. Since the removal of Par's competitors in December 2014, no other manufacturer has marketed a vasopressin product in the United States. During this time, Par has held a monopoly on vasopressin. As a result, Par increased the price of vasopressin from less than five dollars per vial to over one hundred thirty dollars per vial.

E. Par's Reformulated Vasopressin® Product

40. Although competing vasopressin products were removed from the market, the NDA for Original Vasopressin® was not eligible for any regulatory

exclusivity. Without any exclusivity, competitors were free to file their own NDAs or ANDAs to seek approval for competing vasopressin products. Only by listing patents in the Orange Book could Par forestall FDA approval and commercial launch of competitors' products.

41. Given that Par's Original Vasostrict® product was substantively identical to the prior art Pitressin® product that had been sold for almost a century, Par knew that it could not maintain exclusivity for its Original Vasostrict® product for long, as any patent covering the formulation of Original Vasostrict® would necessarily be invalid.

42. Therefore, although Original Vasostrict® had been approved by the FDA and had acceptable stability, Par began to look for ways that it could justify a new formulation of Vasostrict® that could be patented.

43. On March 21, 2016, Par received approval for a new formulation of Vasostrict® ("Reformulated Vasostrict®").

44. The only changes Par made to the formulation were: (1) changing the target pH from 3.4–3.6 to 3.8; (2) removing chlorobutanol; and (3) adding an acetate buffer.

45. Par sought and received the same shelf life for the Reformulated Vasostrict® as was already approved for the Original Vasostrict®.

46. Although Reformulated Vasostrict® has a target pH of 3.8, its release pH specification is [REDACTED] and its shelf-life stability pH specification is [REDACTED]

47. The storage and handling instructions for Reformulated Vasostrict® are the same as for Original Vasostrict®.

48. The dosage and administration section of the prescribing information for Reformulated Vasostrict® is the same as for Original Vasostrict®.

49. The FDA has confirmed that Original Vasostrict® was not removed from the market for safety or efficacy reasons. Par and the named inventors on the Patents-in-Suit could not identify any safety or efficacy advantage of Reformulated Vasostrict® compared to Original Vasostrict®.

F. Par's Patents

1. '239 Patent

50. The Patents-in-Suit each claim priority to the '239 patent, which issued on August 29, 2017 based on an application filed on May 20, 2015. The '239 patent names Vinayagam Kannan and Matthew Kenney as inventors. The Examiner of the '239 patent was Christine Bradley.

51. During prosecution of the '239 patent, Examiner Bradley issued a Final Office Action on October 21, 2015, rejecting all pending claims as both anticipated and obvious over the April 2014 Vasostrict® Label.

52. Instead of amending the claims, the inventors sought to overcome Examiner Bradley's Final Rejection by invoking the prior art exception of 35 U.S.C. § 102(b)(1)(A), which provides in relevant part that disclosures made 1 year or less before the effective filing date of the claimed invention shall not be prior art, "if the disclosure was made by the inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor."

53. During a November 24, 2015 Applicant-Initiated Interview, the inventors' prosecuting attorney, Mr. Craig Kenesky, represented that the named inventors were "responsible for all of the subject matter in the FDA reference [(the April 2014 Vasostrict® Label)]" and would be able to make an "unequivocal" statement to that effect.

54. To that end, the inventors submitted two declarations, one from named inventor Vinayagam Kannan, and one from regulatory employee Michelle Bonomi-Huvala. Mr. Kannan declared under penalty of perjury that he and named co-inventor Matthew Kenney invented all of the subject matter of the April 2014 Vasostrict® Label that Examiner Bradley had relied upon to reject the claims. Ms. Bonomi-Huvala declared that the subject matter of the April 2014 Vasostrict® Label that Examiner Bradley had relied upon to reject the claims had been received from

named inventors Kannan and Kenney, and sent on to the FDA, who published the April 2014 Vasostrict® Label.

55. The Kannan and Bonomi-Huvala declarations were submitted by Mr. Kenesky to the U.S. Patent & Trademark Office (“PTO”) with a Response to Final Rejection on November 24, 2015, in which he represented that the declarations “describe[] that the disclosure of the [April 2014 Vasostrict® Label] was obtained from the inventors of the present application,” and that therefore the April 2014 Vasostrict® Label:

is not prior art under 35 U.S.C. § 102(a)(1) against the present invention based on the exception of 35 U.S.C. § 102(b)(1)(A). The disclosure was made by another (the FDA) less than one year before the effective filing date of the claimed invention. The FDA obtained the subject matter of the Label from the regulatory team at PAR STERILE, who received the subject matter from the inventors of the present application. Thus, the Label satisfies the provisions of 35 U.S.C. § 102(b)(1)(A). Applicant respectfully requests withdrawal of the rejection because the claims have not been rejected over any eligible prior art.

56. Based on these representations, Examiner Bradley withdrew the final rejection of the pending claims over the April 2014 Vasostrict® Label on January 11, 2016. Examiner Bradley never again raised the April 2014 Vasostrict® Label as prior art against the ’239 patent or any of the subsequently filed Patents-in-Suit.

2. ’526 Patent

57. The application that issued as the ’526 patent was filed on October 10, 2016 as a continuation-in-part of the application for the ’239 patent. This was after

Examiner Bradley had disqualified the April 2014 Vasostrict® Label as prior art, and after the approval and marketing of Par's Reformulated Vasostrict® product. Like the '239 patent, the '526 patent also names Vinayagam Kannan and Matthew Kenney as inventors, as well as two other Par employees, Sunil Vandse and Suketu Sanghvi. Like the '239 patent, the '526 patent was examined by Examiner Bradley.

58. Like the '239 patent, the claims of the '526 patent are directed to the use of a vasopressin composition comprising between 0.01 and 0.07 mg/mL vasopressin, acetic acid, and water at a dose of between 0.01 and 0.1 units per minute to increase blood pressure in a hypotensive human. The '526 patent does not recite the same pH range as the '239 patent, but rather claims a specific pH within the range claimed by the '239 patent.

59. Because the inventors had already represented that Vinayagam Kannan and Matthew Kenney had invented the subject matter of April 2014 Vasostrict® Label, Examiner Bradley would have understood that she could not raise the April 2014 Vasostrict® Label as prior art against the application for the '526 patent, on which Kannan and Kenney were both also named inventors.

60. Therefore, Examiner Bradley identified the closest prior art as the label from the unapproved vasopressin formulation sold by Pharmaceutical Partners of Canada (PPC), which identified only the broad pH range of 2.5–4.5 and did not include indications for hypotension.

61. Examiner Bradley entered a final rejection of the pending claims over the PPC reference in view of additional prior art, stating that PPC disclosed the same formulation as that recited by the pending claims of the '526 patent, with the same vasopressin concentration, acetic acid, and water, and an overlapping pH range of 2.5 to 4.5. In subsequent communications, the inventors did not dispute that PPC disclosed such a formulation.

62. Regarding storage, Examiner Bradley stated that it would have been obvious to refrigerate the formulation disclosed in PPC, as had been widespread in the art for a number of other peptide pharmaceutical products. In subsequent communications, the inventors did not dispute that it would have been obvious to refrigerate the formulation of PPC.

63. Examiner Bradley also stated that the formulation of PPC, by virtue of overlapping with that of the claims, inherently satisfied the percent degradation limitation. In subsequent communications, the inventors did not dispute that PPC inherently met the percent degradation over storage limitation.

64. Finally, Examiner Bradley stated that it would have been obvious in view of a number of clinical literature references to administer the formulation disclosed by PPC to treat hypotension in the manner claimed. Among those clinical references was Russell 2008. In subsequent communications, the inventors did not

dispute that it would have been obvious to administer the formulation of PPC to practice the method of treatment limitations.

65. Following the rejection, the inventors held an interview with Examiner Bradley, during which they agreed to add a limitation requiring a pH of 3.8.

66. To that end, the inventors filed amended claims that added the pH 3.8 limitation. Those claims are the ones that ultimately issued, including claim 13 asserted here.

67. The inventors' primary argument to overcome Examiner Bradley's rejection over PPC was that the claimed pH of 3.8 was critical to stability of a vasopressin formulation.

68. Relying on declarations disclosing testing data from named inventors Vinayagam Kannan and Sunil Vandse (the "Criticality Declarations"), the inventors argued that pH 3.8 exhibited unexpected stability within the pH range of 2.5 to 4.5 disclosed in PPC.

69. To make that representation, the Criticality Declarations relied on pH-dependent stability testing that allegedly showed that pH 3.8 had the lowest level of impurities after storage for four weeks at 25 °C and 40 °C. Although other pH levels demonstrated lower relative levels of vasopressin degradation under those storage conditions, the inventors argued that vasopressin formulations were most stable at pH 3.8 in view of those impurities levels.

70. Examiner Bradley accepted this argument based on the alleged critical stability of pH 3.8 and allowed the claims. This was the only reason cited by Examiner Bradley in her Notice of Allowance.

71. Par asserts claim 13 of the '526 patent against Eagle. Claim 13 of the '526 patent depends from claim 1.

72. Claim 13 of the '526 patent, through its dependency on claim 1, recites:

1. A method of increasing blood pressure in a human in need thereof, the method comprising:

a) providing a pharmaceutical composition for intravenous administration comprising: i) from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically-acceptable salt thereof; ii) acetic acid; and iii) water,

wherein the pharmaceutical composition has a pH of 3.8;

b) storing the pharmaceutical composition at 2-8°C. for at least 4 weeks; and

c) intravenously administering the pharmaceutical composition to the human, wherein the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute, wherein the human is hypotensive,

wherein the pharmaceutical composition exhibits less than about 5% degradation after storage at 2-8°C. for about four weeks.

13. The method of claim 1, wherein the pharmaceutical composition exhibits less than 1% degradation after storage at 2-8 C. for about four weeks.

73. Although the '526 patent claims priority to several earlier applications, Par has not disputed that those earlier applications do not adequately support asserted

claim 13 of the '526 patent. The earliest effective filing date of asserted claim 13 of the '526 patent is therefore October 10, 2016.

3. '209 and '785 Patents

74. The applications that issued as the '209 and '785 patents were both filed on February 17, 2017 as continuations-in-part of the application for '526 patent and, by extension, continuations-in-part of the application for the '239 patent. This was after Examiner Bradley had disqualified the April 2014 Vasostrict® Label as prior art during prosecution of the '239 patent, and after the approval and marketing of Par's Reformulated Vasostrict® product. Like the '526 patent, the '209 and '785 patents also name Vinayagam Kannan, Matthew Kenney, Sunil Vandse, and Suketu Sanghvi as inventors. Like the '239 and '526 patents, the '209 and '785 patents were examined by Examiner Bradley.

75. The claims of the '209 patent are similarly directed to the use of vasopressin formulations comprising between 0.01 and 0.07 mg/mL vasopressin at a dose of between 0.01 and 0.1 units/minute to raise blood pressure in hypotensive human. The '209 patent recites a pH range of 3.7 to 3.9 for those vasopressin formulations, broader than the pH limitation of the '526 patent but within the range of the '239 patent.

76. The claims of the '785 patent are directed to the compositions of vasopressin used in the methods of the '209 patent.

77. As with the '526 patent, Examiner Bradley also rejected the pending claims of the '209 and '785 patents over PPC, finding, as she did during prosecution of the '526 patent, that PPC disclosed a formulation with the same vasopressin levels as claimed. She also stated that it would have been obvious to administer that formulation to practice the claimed method according to the '209 patent claims.

78. Examiner Bradley also noted that the pH range recited by the applications for the '209 and '785 patents was encompassed by the pH range of 2.5 to 4.5 in PPC and therefore presumptively obvious.

79. In rejecting the claims over PPC, Examiner Bradley cited the April 2014 Vasostrict® Label as an “evidentiary reference,” making clear to the inventors that the April 2014 Vasostrict® Label need not be “prior art” to be used to provide evidence supporting her analysis of PPC. This confirms that Examiner Bradley understood that she could not raise the April 2014 Vasostrict® Label as prior art against the applications for the '209 and '785 patents due to the declarations submitted during prosecution of the '239 patent, as Kannan and Kenney were both also named inventors.

80. As to impurities, Examiner Bradley found that all such limitations, including those directed to levels of specific impurities found in the dependent claims, were the inherent results of the formulation and therefore disclosed by the PPC formulation. In a subsequent interview, the inventors proposed the current

impurities limitations to distinguish that prior art. Examiner Bradley rejected the inventors' reasoning and concluded that the limitation was still satisfied by PPC's formulation by inherency. The inventors did not dispute that subsequent conclusion.

81. In response to Examiner's Bradley's rejections, the inventors adopted the limitations of the Asserted Claims, including the related impurities limitations, despite the Examiner Bradley's rejection of them in the interview, and a pH of 3.7–3.9.

82. The inventors did not dispute any of Examiner Bradley's findings regarding the PPC reference. Rather, as they had done during the prosecution of the '526 patent, the inventors argued that pH was critical to the Asserted Claims over the range of pH 2.5 to 4.5. Instead of pH 3.8 being critical, as in the '526 patent, the inventors argued that a pH range of 3.7 to 3.9 as recited by the '209 and '785 patent was critical to the stability of vasopressin formulations and exhibited unexpected results over the prior art.

83. In lieu of submitting inventor declarations as in the '239 patent and '526 patent prosecutions, the inventors directed Examiner Bradley to the same data and conclusions from the Criticality Declarations that has been incorporated into

Examples 9 and 10 of the '209 and '785 patents' specifications.² Relying on that same data, the inventors represented to Examiner Bradley that pH 3.7 to 3.9—not just pH 3.8—demonstrated unexpectedly lower impurity levels than, and at least comparable vasopressin degradation levels to, other pH levels in PPC's range.

84. Par asserts claims 1, 3, 4, 5, and 7 of the '209 patent, which require:

1. A method of increasing blood pressure in a human in need thereof, the method comprising administering to the human a unit dosage form, wherein the unit dosage form comprises from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically acceptable salt thereof, wherein: the unit dosage form has a pH of 3.7-3.9; the unit dosage form further comprises impurities that are present in an amount of 0.9% - 1.7%, wherein the impurities have from about 85% to about 100% sequence homology to SEQ ID NO.: 1³; the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute; and the human is hypotensive.

3. The method of claim 1, wherein the impurities comprise SEQ ID NO.: 3,⁴ and SEQ ID NO.: 3 is present in the unit dosage form in an amount of 0.1% .

4. The method of claim 1, wherein the impurities comprise SEQ ID NO.: 4,⁵ and SEQ ID NO.: 4 is present in the unit dosage form in an amount of 0.2% to 0.4%.

² The data in the Criticality Declarations were also incorporated into the specification of the '526 patent as Examples 9 and 10, but the inventors resubmitted the Declarations themselves in the '526 patent prosecution.

³ "SEQ ID NO.: 1" refers to the vasopressin compound.

⁴ "SEQ ID NO.: 3" refers to Asp5-vasopressin compound, a related impurity.

⁵ "SEQ ID NO.: 4" refers to Glu4-vasopressin compound, a related impurity.

5. The method of claim 1, wherein the impurities comprise SEQ ID NO.: 7,⁶ and SEQ ID NO.: 7 is present in the unit dosage form in an amount of 0.3% to 0.6%.

7. The method of claim 1, wherein the impurities comprise SEQ ID NO.: 2⁷ and SEQ ID NO.: 4, and SEQ ID NO.: 2 is present in the unit dosage form in an amount of 0.1% to 0.3% and SEQ ID NO.: 4 is present in the unit dosage form in an amount of 0.2% to 0.4%.

85. Par asserts claims 1, 4, 5, and 8 of the '785 patent, which require:

1. A pharmaceutical composition comprising, in a unit dosage form, from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically-acceptable salt thereof, wherein the unit dosage form further comprises impurities that are present in an amount of 0.9% to 1.7%, wherein the impurities have from about 85% to about 100% sequence homology to SEQ ID NO.: 1, and wherein the unit dosage form has a pH of 3.7-3.9.

4. The pharmaceutical composition of claim 1, wherein the impurities comprise SEQ ID NO.: 3, and SEQ ID NO.: 3 is present in the unit dosage form in an amount of 0.1%.

5. The pharmaceutical composition of claim 1, wherein the impurities comprise SEQ ID NO.: 4, and SEQ ID NO.: 4 is present in the unit dosage form in an amount of 0.2% to 0.4%.

8. The pharmaceutical composition of claim 1, wherein the impurities comprise SEQ ID NO.: 2 and SEQ ID NO.: 4, and SEQ ID NO.: 2 is present in the unit dosage form in an amount of 0.1% to 0.3% and SEQ ID NO.: 4 is present in the unit dosage form in an amount of 0.2% to 0.4%.

86. Although the '209 and '785 patents claim priority to several earlier applications, Par has not disputed that those earlier applications do not adequately

⁶ "SEQ ID NO.: 7" refers to Acetyl-vasopressin compound, a related impurity.

⁷ "SEQ ID NO.: 2" refers to Gly9-vasopressin compound, a related impurity.

support the Asserted Claims of those patents. The earliest effective filing date of the Asserted Claims of the '209 and '785 patents is therefore February 17, 2017.

G. Eagle's ANDA Product

87. The FDA has confirmed that Par's Original Vasostrict® formulation "was not discontinued from sale for reasons of safety or effectiveness," and that the FDA will "receive ANDAs that refer to Vasostrict as the RLD and propose to duplicate the original formulation of Vasostrict, 20 units per mL, and FDA may approve such ANDAs, as long as all other requirements are met."⁸

88. To that end, [REDACTED]

[REDACTED] In other words, [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

89. The prescribing instructions for Eagle's ANDA Product are substantively identical to [REDACTED] except for the change in product name.

⁸ DTX-258 (FDA, Dkt. No. FDA-2017-P-1096, Response to Citizen's Petition at 4-5 (Dec. 21, 2018)).

90. Although Eagle's ANDA Product is [REDACTED]
Eagle's ANDA [REDACTED]
[REDACTED]

91. Par has accused Eagle's ANDA product and its prescribing information of infringing each of the Asserted Claims of the Patents-in-Suit.

92. For the pH limitations, Par relies on [REDACTED]
[REDACTED]

II. EAGLE'S ANDA PRODUCT DOES NOT INFRINGE THE ASSERTED CLAIMS

93. Plaintiffs have not carried their burden of proving that Eagle's ANDA Product, or use thereof, can and/or will meet each and every limitation of the Asserted Claims of the Patents-in-Suit.

94. Claim 13 of the '526 patent and claims 1, 3–5, and 7 of the '209 patent are all method of treatment claims. Eagle does not and will not treat patients with its ANDA Product. Eagle therefore does not and will not infringe claim 13 of the '526 patent and claims 1, 3–5, and 7 of the '209 patent directly.

95. A physician's use of Eagle's ANDA Product according to the associated prescribing information ("Eagle's Label") will not infringe claim 13 of the '526 patent or claims 1, 3–5, and 7 of the '209 patent, because such use will not involve performing the recited method steps using the compositions recited in the claims.

96. The method steps of claim 13 of the '526 patent are not attributable to a single entity having direction and control over all actors performing the method steps, nor are the method steps attributable to a joint enterprise.

97. Eagle will not induce infringement of claim 13 of the '526 patent or claims 1, 3–5, and 7 of the '209 patent because Eagle will not promote, encourage, or recommend performance of the recited method steps using the compositions recited in the claims.

98. Claims 1, 4, 5, and 8 of the '785 patent are all composition claims. Eagle does not and will not make, use, sell, offer to sell, or import the compositions recited in claims 1, 4, 5, and 8 of the '785 patent. Eagle therefore does not and will not infringe claims 1, 4, 5, and 8 of the '785 patent directly.

99. Eagle does not and will not induce infringement of claims 1, 4, 5, and 8 of the '785 patent because Eagle does not and will not promote, encourage, or recommend the making, use, sale, offer for sale, or importation of the compositions recited in the claims.

A. Eagle's ANDA Product [REDACTED]

100. [REDACTED]

[REDACTED]

[REDACTED] as required by the Asserted Claims of the Patents-in-Suit.

1. Eagle's ANDA Precludes a pH of 3.7 to 3.9, or 3.8

101. Eagle's Label for its ANDA Product, which is substantively identical to [REDACTED] except for the change in product name, describes Eagle's ANDA Product as [REDACTED]

[REDACTED]

102. Eagle's ANDA [REDACTED]

[REDACTED]

[REDACTED]

103. Eagle's ANDA [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

2. Eagle's ANDA Batch Data Do Not Show that Eagle's ANDA Product Will Have [REDACTED] During Its Shelf Life

104. As part of its application for FDA approval to market a generic version of [REDACTED] Eagle, in conjunction with Albany Molecular Research Inc. ("AMRI"), commissioned the manufacture of [REDACTED] batches of its proposed ANDA Product: [REDACTED]

[REDACTED]

EXHIBIT 3

[REDACTED]

[REDACTED]

105. Batches [REDACTED] were each put on stability under the labeled storage conditions Eagle has proposed for its ANDA Product, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

106. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

107. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

EXHIBIT 3

108. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

109. [REDACTED]

[REDACTED]

[REDACTED]

110. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

111. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].

112. [REDACTED]

[REDACTED]

[REDACTED]

EXHIBIT 3

[REDACTED]

[REDACTED]

113. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

114. [REDACTED]

[REDACTED]

EXHIBIT 3

A series of horizontal black bars of varying lengths and positions, resembling a barcode or a stylized text representation. The bars are arranged in a vertical sequence, with some starting from the left edge and others indented. The lengths vary significantly, with some bars spanning most of the width and others being much shorter. The overall effect is a rhythmic, abstract pattern of solid black shapes against a white background.

128. [REDACTED]

[REDACTED]

[REDACTED]

129. [REDACTED]

[REDACTED]

[REDACTED]

130. Par did not perform any testing on Eagle's ANDA Product.

3. Eagle's [REDACTED] Proposed Commercial Product Will Maintain [REDACTED] During Its Shelf Life

131. There is no evidence that Eagle intends physicians to administer a vasopressin composition having a pH of 3.7 to 3.9, or 3.8, according to the claimed methods. Further, there is no evidence that Eagle intends to make, use, or sell a vasopressin product having a pH of 3.7 to 3.9, as required by claim 1 of the '785 patent.

132. [REDACTED]

[REDACTED]

133. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

35

EXHIBIT 3

136. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

137. [REDACTED]

[REDACTED]

138. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

139. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

140. Par has provided no evidence to the contrary.

141. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

142. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

4. There is No Evidence That Eagle's ANDA Product Will Be Stored for Four Weeks at pH 3.8

143. Eagle's Label, which describes Eagle's ANDA Product [REDACTED]
[REDACTED] does not provide any instruction or recommendation to store Eagle's ANDA Product for at least four weeks prior to administration.

144. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

145. Par did not perform any testing on Eagle's ANDA Product.

146. Additionally, Eagle's ANDA Product would not be administered to any patient after the end of its proposed shelf life; rather, pharmacists will discard Eagle's ANDA Product according to the shelf life described in Eagle's Label, [REDACTED]

[REDACTED]

[REDACTED]

5. Eagle's ANDA Product Will Not Be Used by a Single Entity to Practice the Claims of the '526 patent

147. Claim 13 of the '526 patent has several distinct method steps: storing the recited formulation for at least about four weeks at 2–8°C; providing the recited formulation; and administering the recited formulation to increase blood pressure in a hypotensive human.

148. Upon approval, Eagle's ANDA Product will be stored, provided, and administered by different entities. Hospital pharmacists will acquire Eagle's ANDA Product and store that product, including under refrigeration. When needed, those same pharmacists will distribute Eagle's ANDA Product to physicians for administration to patients.

149. On the other hand, physicians would alone be responsible for the administration of Eagle's ANDA Product after approval. Only a physician may exercise medical judgment to determine that the administration of vasopressin is warranted to treat vasodilatory shock. Once a physician examines a patient and, in his or her independent judgment, decides to use vasopressin, the administration of that drug proceeds according to the physician's order and under the physicians supervision.

150. Par has not shown that the activities of pharmacists in storing Eagle's ANDA Product are attributable to the physicians who would be responsible for the administration of Eagle's ANDA Product. For physicians, the first time they handle Eagle's ANDA Product is when it is to be administered to a patient. Physicians have no role in the storage of Eagle's ANDA Product at any point before that time and do not direct and control that process. Physicians may serve on hospital committees that decide which drugs to acquire and may recommend best practices, but at no point do such hospital committees oversee the storage of particular products such as Eagle's ANDA Product and specific units thereof.

151. Par has not shown that pharmacists will have a role in the use of Eagle's ANDA Product. Physicians exercise independent medical judgment in deciding to administer Eagle's ANDA Product, including at a particular dose. Indeed, it would be unlawful and contrary to established medical ethics for any individual to direct

and control a clinician's use of Eagle's ANDA Product to treat a patient, including with respect to dose and timing. Pharmacists cannot direct and control a physician's use of Eagle's ANDA Product to treat hypotension.

152. Par has not shown that hospitals are a single entity that directs and controls the storing, providing, and administration of Eagle's ANDA Product. Although pharmacists and other staff may be employed directly by hospitals, the physicians who will use Eagle's ANDA Product are typically independent contractors. As independent contractors, physicians using Eagle's ANDA Product will not be subject to the direction and control of the hospital or its staff in the actual use and administration of Eagle's ANDA Product. Such contracts are silent regarding the use of any drug, let alone requirements regarding the performance of particular method steps using Eagle's ANDA Product. Such contracts also do not override doctors' independent medical judgment in treating patients.

153. The services of the physicians who use Eagle's ANDA Product and the provision of drugs for that use are billed separately to insurers and patients. Hospitals bill for the provision of supplies, including pharmaceuticals like Eagle's ANDA Product. Physicians provide individualized bills for their services, which may include their diagnosis of patients and their administration of treatment, including drugs, to those patients.

154. Even where physicians are directly employed by hospitals, they still act independently to diagnose patients and prescribe treatments, including the use and administration of a drug like Eagle's ANDA Product. Hospitals and their personnel do not direct the use and administration of drugs like Eagle's ANDA Product in any particular instance of treatment.

155. To the extent that personnel other than doctors, such as nurses, are involved in the administration of Eagle's ANDA Product to treat particular patients, they act under the direction and control of physicians, not hospitals. Even if employed directly by hospitals, such action is an extension of physicians' own independent medical treatment and the performance of particular methods using Eagle's ANDA Product is not done at the direction and control of the hospital.

B. Eagle's ANDA Product Will Not Meet the Claimed Degradation and Impurity Requirements

1. Eagle Will Not Induce Infringement of the Claimed Degradation and Impurity Requirements

156. [REDACTED]
[REDACTED] at the end of the product shelf life. Eagle's ANDA Product would not be administered to any patient after the end of its proposed shelf life; rather, pharmacists will discard Eagle's ANDA Product according to the shelf life described in Eagle's Label, [REDACTED]

2. Eagle's ANDA Does Not Establish Eagle's ANDA Product Will Meet the Claimed Degradation and Impurity Requirements

157. As set forth above, Eagle's ANDA [REDACTED] [REDACTED] throughout its proposed shelf life, not 3.7 to 3.9, or 3.8, as required by the Asserted Claims of the Patents-in-Suit. *See supra* Section II.A.1.

158. Eagle's ANDA specification does not show that Eagle's ANDA Product will necessarily exhibit less than 1% degradation after four weeks storage at 2–8°C, as Eagle's ANDA [REDACTED] [REDACTED] *See* '526 patent claim 13. Rather, Eagle's ANDA [REDACTED] [REDACTED] [REDACTED] [REDACTED]

159. Nor does Eagle's ANDA specification for total impurities show that Eagle's ANDA Product will necessarily comprise 0.9% to 1.7% impurities having 85% to 100% sequence homology to vasopressin. '209 patent claim 1; '785 patent claim 1.

160. Eagle's ANDA [REDACTED] [REDACTED] Eagle's ANDA specification does not

show that Eagle's ANDA Product will necessarily comprise 0.1% SEQ ID No.: 3.

See '209 patent claim 3; '785 patent claim 4.

161. Eagle's ANDA specification [REDACTED]

[REDACTED] Eagle's ANDA specification does not show that Eagle's ANDA Product will necessarily comprise 0.2% to 0.4% SEQ ID No.: 4. *See* '209 patent claim 4; '785 patent claim 5.

162. Eagle's ANDA specification [REDACTED]

[REDACTED] Eagle's ANDA specification does not show that Eagle's ANDA Product will necessarily comprise 0.3% to 0.6% SEQ ID No.: 7. *See* '209 patent claim 5.

163. Eagle's ANDA specification [REDACTED]

[REDACTED] Eagle's ANDA specification does not show that Eagle's ANDA Product will necessarily comprise 0.1% to 0.3% SEQ ID No.: 2. *See* '209 patent claim 7; '785 patent claim 8.

164. Eagle's ANDA specification [REDACTED]

[REDACTED] Eagle's ANDA specification does not show that Eagle's ANDA Product will necessarily comprise 0.1% to 0.3% SEQ ID No.: 2 and 0.2% to 0.4% SEQ ID No.: 4. *See* '209 patent claim 7; '785 patent claim 8.

3. Eagle's ANDA Batch Data Do Not Show that Eagle's ANDA Product Will Exhibit "Less Than 1% Degradation" After Storage at 2–8°C For Four Weeks at pH 3.8

165. As set forth above, Eagle's ANDA batch data do not show Eagle's ANDA Product will have a pH of 3.8 during its shelf life. *See supra* Section II.A.2.

166. [REDACTED]

[REDACTED] *See* '526 patent claim 1; *see also supra* Section II.A.4.

167. [REDACTED]

[REDACTED]

168. [REDACTED]

[REDACTED].

169. [REDACTED]

[REDACTED]

[REDACTED]

170. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

171. [REDACTED]

[REDACTED]

172. [REDACTED]

[REDACTED]

[REDACTED]

173. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

174. Par did not perform any testing on Eagle's ANDA Product.

4. Eagle's ANDA Batch Data Do Not Show that Eagle's ANDA Product Will Have the Specified Impurities

175. As set forth above, Eagle's ANDA batch data do not show Eagle's ANDA Product will have a pH of 3.7–3.9 during its shelf life. *See supra* Section II.A.2.

176. Impurity data provided in Eagle's ANDA [REDACTED]

[REDACTED]

[REDACTED] does not show that Eagle's ANDA Product will meet the specified impurity limitations.

177. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

178. Par did not perform any testing on Eagle's ANDA Product.

a. **0.1% SEQ ID No.: 3 ('209 patent claim 3; '785 patent claim 4)**

179. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

EXHIBIT 3

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

189. [REDACTED]

[REDACTED]

[REDACTED]

190. [REDACTED]

[REDACTED]

[REDACTED]

c. 0.1% to 0.3% SEQ ID No.: 2 and 0.2% to 0.4% SEQ ID No.: 4 ('209 patent claim 7; '785 patent claim 8)

191. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

192. [REDACTED]

[REDACTED]

III. THE ASSERTED CLAIMS OF THE PATENTS-IN-SUIT ARE UNENFORCEABLE FOR INEQUITABLE CONDUCT

193. The named inventors Vinayagam Kannan and Matthew Kenney, Par's former Senior Vice President of Regulatory Affairs Michelle Bonomi-Huvala and Par's patent prosecution counsel Craig Kenesky knowingly submitted unmistakably false declarations to the PTO to overcome the Examiner's rejection of the pending claims of the application for the '239 patent, which are presumed to be material and submitted with an intent to deceive.

194. Even absent the presumption, the unmistakably false Kannan and Bonomi-Huvala declarations were material to the prosecution of the '239 patent, and were submitted with an intent to deceive.

195. The inequitable conduct committed during prosecution of the '239 patent, which is a parent or grandparent patent application to the Patents-in-Suit, infected the prosecution of the Patents-in-Suit and therefore renders the claims of those patents unenforceable under the doctrine of infectious unenforceability.

196. In addition, one or more of the named inventors of the Patents-in-Suit knowingly withheld material information from the PTO during prosecution of the Patents-in-Suit, including prior art, internal testing data, and other information that

would have undermined their assertions of the criticality of the claimed pH, with the specific intent to deceive the PTO.

A. Inequitable Conduct During Prosecution of the '239 Patent

197. Faced with a final rejection in light of the prior art April 2014 Vasostrict® Label, named inventor Vinayagam Kannan, Par's former Senior Vice President of Regulatory Affairs Michelle Bonomi-Huvala and prosecuting attorney Craig Kenesky knowingly submitted unmistakably false declarations to the PTO in order to overcome the prior art rejection. These declarations were submitted with the specific intent to deceive the PTO to secure the issuance of the '239 patent.

198. Mr. Kannan, Ms. Bonomi-Huvala, and Mr. Kenesky all knew that the executed Kannan and Bonomi-Huvala declarations, as well as the representations made by Mr. Kenesky to the Examiner as to those declarations, were false.

199. Mr. Kenney [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

200. Mr. Kannan [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

201. Mr. Kannan [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

202. Thus, the representations made in the Kannan declaration are unmistakably false, and Mr. Kannan knew that they were false at the time he signed and submitted his declaration to the PTO.

203. Indeed, according to Par's corporate witness and discovery responses,

[REDACTED]

[REDACTED]

[REDACTED]

204. The Bonomi-Huvala declaration was also unmistakably false, as the named inventors of the '239 patent never "forwarded the details of the joint invention [(i.e. the subject matter of the April 2014 Vasostrict® Label)] to the regulatory team at PAR STERILE."

205. Mr. Bonomi-Huvala [REDACTED]

[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]

206. Mr. Kenesky, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

207. Nevertheless, Mr. Kenesky [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

208. No one involved in the prosecution of the '239 patent or otherwise advised Examiner Bradley that the representations made in the Kannan and Bonomi-Huvala declarations were false.

209. Furthermore, Examiner Bradley had no ability to independently examine the facts of the Kannan and Bonomi-Huvala declarations because they relied on research and development and communications that were internal and confidential to Par.

210. These false representations to the PTO constitute affirmatively egregious misconduct.

211. But-for these false representations, the '239 patent never would have issued, as Examiner Bradley's Final Rejection would not have been overcome without the false declarations. Indeed, the April 2014 Vasostrict® Label anticipates and/or renders obvious every claim of the '239 patent.

212. Given the strength of Examiner Bradley's rejection in light of the April 2014 Vasostrict® Label, and the subsequent false representations made by the inventors to disqualify that prior art reference, the single most reasonable inference is that Mr. Kenesky, Mr. Kannan, and Ms. Bonomi-Huvala submitted the

unmistakably false declarations with the specific intent to deceive the PTO to secure the issuance of the '239 patent.

B. Inequitable Conduct During Prosecution of the '239 Patent Renders the Patents-in-Suit Unenforceable

213. The affirmative egregious misconduct committed by Mr. Kenesky, Mr. Kannan, and Ms. Bonomi-Huvala during prosecution of the '239 patent renders unenforceable the Patents-in-Suit under the doctrine of infectious unenforceability.

214. Because Vinayagam Kannan and Matthew Kenney were named inventors on each of the Patents-in-Suit, Examiner Bradley would have believed that she could not rely on the April 2014 Vasostrict® Label as prior art during prosecution of those patents, as evidenced by the fact that she cited the April 2014 Vasostrict® Label in support of her rejection of the claims of the '209 and '785 patents, but only as an “evidentiary reference.” In so doing, Examiner Bradley stressed that such an “evidentiary reference” need not qualify as prior art. Therefore, it is clear that the misconduct during the prosecution of the '239 patent infected those of the Patents-in-Suit and renders them unenforceable.

215. Unable to rely on the April 2014 Vasostrict® Label, the next closest prior art Examiner Bradley identified was PPC combined with Russell 2008, among other references, in rejecting the claims of the Patents-in-Suit. Examiner Bradley rejected the pending claims' pH limitations of 3.8 or 3.7–3.9 as presumptively obvious over PPC's range of pH 2.5 to 4.5.

216. The inventors were only able to overcome this rejection by relying on the flawed data in the Criticality Declarations. The inventors resubmitted the Criticality Declarations during the prosecution of the '526 patent and relied on the same data as set forth in the '209 and '785 patents' specifications during the prosecutions of those patents.

217. The April 2014 Vasostrict® Label was material to the prosecution of, and would have invalidated as anticipated and/or obvious, each of the claims of the Patents-in-Suit. The April 2014 Vasostrict® Label discloses a narrower pH range of 3.4–3.6 than PPC, as well as several other limitations not found in PPC or Treschan.

218. Further, the data relied on by the inventors would have been insufficient to show the criticality of the claimed pHs between 3.7 and 3.9 over the pH range 3.4–3.6 in the April 2014 Vasostrict® Label, and the inventors would not otherwise have been able to establish criticality over the formulation described in that label.

219. This is especially true, given that [REDACTED]
[REDACTED] the prior art Original Vasostrict® product, which is embodied by the April 2014 Vasostrict® Label.

C. The Named Inventors Committed Further Inequitable Conduct During Prosecution of the Patents-in-Suit

1. The Inventors Withheld Material Information Regarding the Prior Art Pitressin® Formulation

220. While attempting to demonstrate the criticality of the claimed pH range in the Patents-in-Suit, the inventors also knowingly withheld material information from the PTO.

221. First, the inventors withheld material information regarding the prior art Pitressin® formulation, which also was formulated with a pH of [REDACTED]. The only difference between Pitressin® and the subsequently released Original Vasostrict® described in the April 2014 Vasostrict® Label was that Pitressin® included [REDACTED]

[REDACTED]

222. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

223. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

224. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

225. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

226. The single most reasonable inference is that the named inventors withheld [REDACTED] with the specific intent to deceive the PTO to secure the issuance of the Patents-in-Suit.

2. The Named Inventors Withheld from the PTO Normalized Impurity Data to Bolster Their Criticality Arguments

227. Among the flaws in the Criticality Declarations, the underlying studies used vasopressin samples with different starting amounts of impurities and vasopressin assay. In particular, the study of the pH range 2.5 to 3.4 was conducted later than the study of the pH range 3.5 to 4.5, when the API lot had expired and the starting levels of impurities were significantly higher.

228. For example, the test composition used for pH of 2.5 started with initial impurity levels of 2.48%, whereas the test composition used for pH of 3.8 started with initial impurity levels of only 0.74%.

229. To account for the differences in the starting impurity levels, it was necessary to normalize the data for both impurities and vasopressin assay. Indeed, the Criticality Declarations stated that normalization was important for this very reason, and represented that all variables other than pH had been normalized. But that representation was false. The only variable that had been normalized in the Criticality Declarations was the vasopressin assay; the impurity levels were not normalized.

230. The named inventors were in possession of normalized impurity data and plots before and during prosecution of the Patents-in-Suit. The normalized impurity data, however, were withheld from the Examiner, and the inventors instead submitted non-normalized impurity data and plots.

231. The normalized impurity data that Mr. Kannan and Mr. Kenney withheld from the PTO contradicted the inventors' arguments that the claimed pHs between 3.7 and 3.9 are critical, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

232. But-for the inventors' actions of withholding the normalized impurity data, Examiner Bradley could not reasonably have found the claimed pH values

critical during prosecution of the Patents-in-Suit. Therefore, the withheld normalized impurity data was material to the patentability of the Patents-in-Suit.

233. The single most reasonable inference that can be drawn from the selective withholding of the normalized impurity data is that the inventors only produced data that supported their criticality arguments, with a specific intent to deceive the PTO to grant the Patents-in-Suit.

3. The Named Inventors Withheld from the PTO Other Information Relevant to Criticality of the Claimed pH That Was Material to the Prosecution

234. [REDACTED]

[REDACTED]

235. [REDACTED]

[REDACTED]

236. [REDACTED]

[REDACTED]

[REDACTED]

237. [REDACTED]

[REDACTED]

[REDACTED]

238. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

239. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

240. In addition, the inventors also withheld information relating to the variability in the analytical method used to measure that data underlying the Criticality Declarations from the Examiner.

241. For example, the named inventors failed to inform the PTO that, in the data reported in the Criticality Declarations, the purported difference in impurity

levels between a pH of 3.6 and 3.8, which amounts to no more than 0.13%, is more than an order of magnitude less than the inherent variability of the testing method itself (e.g., 2.0%).

242. The Criticality Declarations neither disclose nor account for this inherent variability. Nor did the named inventors otherwise disclose this variability to the PTO because such information would have directly undermined the inventors' arguments that the claimed pHs between 3.7 and 3.9 are critical over the pH range of 2.5–4.5 disclosed by PPC.

243. Had Examiner Bradley been informed of the inherent variability present in the data points, she could not reasonably have accepted the inventors' representation that the claimed pH ranges and pH are critical over the prior art pH range of 3.4–3.6.

244. The single most reasonable inference that can be drawn from the withholding of the variability present in the data points provided in the Criticality Declarations is that the inventors specifically intended to deceive the PTO to secure the issuance of the Patents-in-Suit.

IV. THE ASSERTED CLAIMS OF THE PATENTS-IN-SUIT ARE INVALID

A. All Asserted Claims Are Anticipated by Original Vasostrict® With Its Prescribing Information

245. Original Vasostrict® was sold with its prescribing information (including at least the September 2014 and March 2015 Vasostrict® Labels), and used in accordance with that prescribing information, before the effective filing dates of the Patents-in-Suit. It is therefore prior art to those Patents-in-Suit.

246. Par has alleged that Eagle's ANDA product, and/or use thereof, infringes each asserted claim of the Patents-in-Suit.

247. [REDACTED]

[REDACTED]

248. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

249. [REDACTED]

[REDACTED]

[REDACTED]

250. [REDACTED]

[REDACTED]

251. The degradation requirement of the '526 patent, and the impurity requirements of the '209 and '785 patents, are merely inherent results of the claimed formulations.

252. Original Vasostrict®, according to its prescribing information, including at least the September 2014 Vasostrict® Label and March 2015 Vasostrict® Label, was sold and used to treat hypotension at a dose of between 0.01 and 0.07 units/minute.

253. Therefore, [REDACTED]
[REDACTED] that claim is invalid as anticipated by Original Vasostrict®

B. All Asserted Claims Are Obvious Over Original Vasostrict® With Its Prescribing Information

254. To the extent that any asserted claim of the Patents-in-Suit is not anticipated by Original Vasostrict®, it would have been obvious over Original Vasostrict®.

255. The pH limitations were at the very least obvious because pH optimization was a standard part of any formulation development process, and Par's own expert has admitted that pH optimization was routine as of the effective filing dates of the Patents-in-Suit.

256. The degradation limitation of the '526 patent, and impurities limitations of the '209 and '785 patents, are merely the inherent results of optimizing the pH

limitations, or at the very least would have been readily achieved through standard formulation development procedures, including choice of pure vasopressin API and appropriate storage conditions, and a POSA would have had a reasonable expectation of success in achieving the claimed degradation and impurity limits. Par's expert has admitted that it would have been obvious to select pure vasopressin API for a pharmaceutical formulation.

257. The evidence submitted by Par is insufficient to show that a pH within the claimed range is critical to stability of a vasopressin formulation, particularly as interpreted by Par for infringement to include achieving the pH at any point in the shelf-life for no more than five minutes. In particular, the data in the Criticality Declarations suffer from myriad flaws and are unreliable. The underlying experiments were conducted with different starting materials and variables such as impurities levels were not controlled, precluding any meaningful comparison. Such data also fail to meet the standard for demonstrating criticality, including showing a difference in kind, not just degree, relative to the prior art. Instead, the inventors' criticality data show at most minor differences in impurity levels over the prior art, which are not commensurate with the scope of the claims.

258. Par also has not shown that the prior art taught away from the claimed pH range; rather, the FDA Bioequivalence Review it relies on at most states that an initial pH of 3.4–3.6 yields optimal stability, while Par asserts that its claims cover

a formulation, such as that of Eagle's ANDA Product, that has [REDACTED]

[REDACTED] Furthermore, contrary to Par's teaching away arguments, other vasopressin formulations were made to a target pH of 3.8, including Lithuanian Patent No. 4487 and [REDACTED]

259. Par has not alleged that any secondary considerations demonstrate the non-obviousness of the claimed formulations.

C. The Asserted Claims of the '785 Patent Are Anticipated by Pitressin®

260. Pitressin® was sold with its prescribing information (including the Pitressin® 2010 Label and Pitressin® 2012 Label) and used both in accordance with that labeling and according to the prevailing off-label use for the treatment of hypotension, including septic shock and post-cardiotomy shock. It is prior art to the claims of the '785 patent.

261. [REDACTED]

[REDACTED]

[REDACTED] the prior art Pitressin® product contained a vasopressin concentration within the Asserted Claims.

262. [REDACTED]

[REDACTED]

263. [REDACTED]

[REDACTED]

264. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

265. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

D. All Asserted Claims Are Obvious over Pitressin®, Alone Or In Combination With Russell 2008, Intravenous Medications 2013, and WHO Standard

266. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

267. [REDACTED]

[REDACTED]

268. [REDACTED]

[REDACTED]

[REDACTED]

269. To the extent Pitressin® did not already satisfy the degradation limitation of the '526 patent and impurities limitations of the '209 and '785 patents, they are merely the inherent results of optimizing the pH limitations. At the very least, these formulation properties would have been readily achieved by a POSA through the routine formulation development process, including using low-impurity vasopressin API and appropriate storage conditions. Using those techniques, a POSA would have had a reasonable expectation of success in achieving the claimed degradation and impurity limits. Par's expert further admitted that it would have been obvious to select pure vasopressin API for a pharmaceutical formulation.

270. Although Pitressin® was not indicated for the treatment of hypotension, such off-label use was widespread. Par has admitted that Pitressin® was used to treat hypotension at an intravenous dose of between 0.01 and 0.1 units/minute.

271. Scholarly articles regarding clinical trials like Russell 2008 and standard handbooks like Intravenous Medications 2013 also taught the use of Pitressin® and other vasopressin products at an intravenous dose of between 0.01 and 0.1 units/minute to treat hypotension. Such guidance renders the use of Pitressin® to practice the recited methods of treatment obvious. Par does not dispute that it would have been obvious to administer Pitressin® according to the recited methods.

272. Although Pitressin® was labeled for room temperature storage, refrigerating Pitressin® would have been obvious as of the earliest effective filing dates. Refrigeration of aqueous peptide pharmaceutical products was and remains a routine practice and, as of the earliest effective filing dates of the Patents-in-Suit, all commercially available vasopressin products were refrigerated. References such as WHO Standard for vasopressin further taught that vasopressin products should be refrigerated to maximize stability, including in the analogous context of preparing standard formulations for analysis. Par's expert has also admitted that a POSA would have expected refrigeration to result in greater stability, less degradation, and fewer impurities, than room temperature storage.

273. Par's evidence does not establish any criticality over Pitressin® or teaching away from the recited pH limitations for the same reasons set forth above.

E. All Asserted Claims Are Obvious Over The April 2014 Vasostrict® Label

274. The April 2014 Vasostrict® Label was published in April 2014 and is therefore prior art to the Asserted Claims.

275. [REDACTED]

[REDACTED] Accordingly, the formulation disclosed by the April 2014 Vasostrict® Label [REDACTED]

[REDACTED] Save for storage conditions, the April 2014 Vasostrict® Label is [REDACTED]

[REDACTED]

276. As with the other prescribing information for Original Vasopressin® and [REDACTED] the April 2014 Vasopressin® Label discloses the formulation of Original Vasopressin® as well as its use to treat hypotension at an intravenous dose of between 0.01 and 0.07 units/minute.

277. To the extent the formulation described by the April 2014 Vasopressin® Label does not have the same pH as the formulations of the Asserted Claims, any such difference is the obvious result of routine optimization, a standard process that Par's expert admits was routine in the field as of the earliest effective filing dates.

278. The Asserted Claims of the '209 and '785 patent are presumptively obvious over the abutting pH range taught by the April 2014 Vasopressin® Label.

279. The degradation limitations of the '526 patent and the impurities limitations of the '209 and '785 patents are merely inherent results of the claimed formulations and the vasopressin composition taught by the April 2014 Vasopressin® Label would achieve them. Indeed, Examiner Bradley found that the April 2014 Vasopressin® Label inherently taught the levels of the impurities specified in the '209 and '785 patent in connection with the prosecution of the '239 patent.

280. Furthermore, a POSA would have achieved those properties through the routine formulation process, including the selection of high-purity vasopressin API for the formulation and appropriate storage conditions. Par's expert has admitted that such steps would have been obvious to a POSA.

281. Although labeled for room temperature storage, it would have been obvious to improve the shelf life and stability of the formulation described in the April 2014 Vasostrict® Label by refrigerating it, including for the same reasons as discussed for Pitressin®. Par's expert has admitted that a POSA would have expected refrigeration to improve stability.

282. Par's evidence does not establish any criticality over the April 2014 Vasostrict® Label or teaching away from the recited pH limitations for the same reasons set forth above.

F. All Asserted Claims Are Obvious Over American Regent Vasopressin Injection, Alone Or In Combination With Russell 2008 and Intravenous Medications 2013.

283. American Regent Vasopressin Injection was sold with its prescribing information and used to treat patients before the earliest effective filing dates of the Asserted Claims. American Regent Vasopressin Injection is therefore prior art.

284. American Regent Vasopressin Injection had the same formulation as the recited claims, including the allegedly critical pH of [REDACTED]. Indeed, American Regent Vasopressin Injection was adjusted to pH [REDACTED] during manufacture at least twenty years prior to the earliest effective filing dates of the Asserted Claims.

285. By virtue of having the same formulation as the Asserted Claims, including [REDACTED] American Regent Vasopressin Injection necessarily achieved the degradation limitations of the '526 patent and the impurities limitations of the

'209 and '785 patent. To the extent American Regent Vasopressin Injection did not satisfy those claim limitations, the Asserted Claims cannot comply with the requirements of Section 112 because the Patents-in-Suit disclose no more than the same formulation.

286. Furthermore, it would have been obvious to prepare the American Regent Vasopressin Injection formulation using high-purity API or to store American Regent Vasopressin Injection in accordance with its labeling under refrigeration to minimize degradation impurities levels. By doing so, a POSA would have achieved the claimed degradation and impurities limitations with a reasonable expectation of success.

287. The American Regent Vasopressin Injection package insert instructed users to store that formulation above freezing (0 °C) but below 23 °C. Contrary to Par's position that a POSA would have understood this to mean room temperature storage, refrigerated storage at 2–8 °C is within that range and consistent with how all commercial vasopressin formulations were stored as of the earliest effective filing dates of the Patents-in-Suit.

288. As with Pitressin®, it would have been obvious to administer American Regent Vasopressin Injection to treat hypotension at an intravenous dose between 0.01 and 0.1 units/minute. Par does not dispute that using American Regent

Vasopressin Injection to practice the recited methods of treatment would have been obvious.

G. All Asserted Claims Are Obvious Over PPC, Alone Or In Combination With Russell 2008, Intravenous Medications 2013, and WHO Standard

289. PPC is a vasopressin injection package insert that was published in 2009. PPC was distributed with Pharmaceutical Partners of Canada's vasopressin product from that time. PPC is prior art.

290. PPC discloses a vasopressin formulation with a pH of 2.5 to 4.5. That pH range encompasses those of the Asserted Claims and renders them presumptively obvious.

291. The pH limitations were at the very least obvious because pH optimization was a standard part of any formulation development process, particularly over the pH range of PPC, and Par's own expert has admitted that pH optimization was routine as of the effective filing dates of the Patents-in-Suit.

292. As Examiner Bradley found during prosecution, PPC's formulation inherently satisfies the degradation and impurities limitations of the Asserted Claims by virtue of having the same ingredients as the claims and an overlapping pH range. During prosecution, the inventors did not dispute the finding that PPC inherently disclosed those limitations.

293. Regardless, a POSA would have had a reasonable expectation of success in achieving low degradation and impurity levels consistent with the claims of the Patents-in-Suit through the routine formulation process, such as by using commercially available low-impurity vasopressin API.

294. It would also have been obvious to store the PPC formulation under refrigeration, as with Pitressin®. Refrigeration of aqueous peptide pharmaceutical products is a routine practice and, as of the earliest effective filing dates, all commercially available vasopressin products were refrigerated. References such as WHO Standard for vasopressin further taught that vasopressin products should be refrigerated to maximize stability, including in the analogous context of preparing standard formulations for analysis. Par's expert has also admitted that a POSA would have expected refrigeration to result in greater stability, and less degradation and fewer impurities, than room temperature storage.

295. Consistent with the teachings in the art and the standard knowledge of POSAs, Examiner Bradley found during prosecution that it would have been obvious to refrigerate the formulation disclosed by PPC. The inventors did not dispute that finding.

296. Administering the PPC formulation according to the standard uses in the art, as taught by references like Russell 2008 and Intravenous Medications 2013, would also have been obvious. Par does not dispute that it would have been obvious

to administer the PPC formulation to practice the recited method of treatment. Additionally, Examiner Bradley specifically found that it would have been obvious to administer the formulation disclosed by PPC to increase blood pressure in hypotensive humans in view of such references as Russell 2008, a finding the inventors did not dispute.

297. Par's evidence does not establish any criticality over PPC or teaching away from the recited pH limitations for the same reasons set forth above.

H. All Asserted Claims Lack Adequate Written Description

1. '526 Patent

298. Claim 13 of the '526 patent is invalid for lack of written description because the specification does not describe the composition recited in claim 1, from which claim 13 depends, that is stored at 2–8°C for at least four weeks and that exhibits “less than 1% degradation after storage at 2-8° C. for about four weeks.”

299. Specifically, there is no description of a vasopressin composition having a pH of 3.8 that was stored at 2–8°C for at least four weeks that exhibits “less than 1% degradation after storage at 2-8° C. for about four weeks.”

300. To the extent it would not have been obvious to store prior art vasopressin compositions at 2–8°C, then there is no indication in the specification that the composition recited in claim 1 was, or should have been, stored at 2–8°C. Further, to the extent a POSA would not have had an expectation of achieving less

than 1% degradation after storing a prior art vasopressin product at 2–8°C for about four weeks, then similarly, there is no indication that storing any of the compositions recited in the examples in the specification would have achieved less than 1% degradation after storage at 2–8°C for about four weeks.

301. Claim 13 of the '526 patent is additionally invalid for lack of written description because the specification does not describe the full scope of the claimed compositions.

302. Claim 13 of the '526 patent broadly covers any vasopressin composition that has a pH of 3.8, that is formulated with acetic acid, and has less than 1% degradation after storage at 2–8°C for about four weeks.

303. There is no disclosure in the specification evidencing that the inventors were in possession of a vasopressin composition having a pH of 3.8 formulated with acetic acid only, which is the only excipient specifically recited by the claims of the '526 patent, where that composition exhibited less than 1% degradation after storage at 2–8°C for about four weeks.

304. The verbatim disclosure of certain claim limitations of the '526 patent does not provide written description support as these disclosures do not identify the pH of the composition.

305. The specification provides a broad range of acceptable pH ranges, ranging from 2.0 to 5.0.

306. The verbatim disclosure of certain claim limitations of the '526 patent also does not provide data supporting the requirement that the composition exhibit less than 1% degradation after storage at 2–8°C for about four weeks.

307. The only disclosures in the specification of a vasopressin composition having a pH of 3.8 were formulated with a buffer.

308. The only disclosures in the specification of a vasopressin composition having a pH of 3.8 that provide stability data were for vasopressin compositions formulated with acetate buffer.

309. The vasopressin compositions formulated with acetate buffer were stored at 25°C and 40°C, not 2–8°C as required by the claims of the '526 patent.

310. The '526 patent does not require use of an acetate buffer. The claims are broad enough to cover formulations, such as American Regent Vasopressin Injection, that are formulated with acetic acid only, not acetate buffer, for which Par's expert claims there would not have been a reasonable expectation of success achieving the claimed degradation limitation.

311. The '526 patent lacks written description of the full scope of the claimed compositions.

2. '209 and '785 Patents

312. The '209 and '785 patents are invalid for lack of written description because the specifications do not describe the full scope of the claimed compositions.

313. The '209 and '785 patents broadly cover any vasopressin composition that has a pH of 3.7 to 3.9 and has 0.9% to 1.7% impurities having 85% to 100% sequence homology to vasopressin.

314. The only disclosures in the specification of a vasopressin composition having a pH of between 3.7 and 3.9 were formulated with a buffer.

315. The majority of these disclosures do not provide any stability data evidencing that the compositions achieved the claimed impurity levels.

316. The specification discloses only a single vasopressin composition having a pH of between 3.7 and 3.9 and formulated with an acetate buffer that provides individual impurity data.

317. Neither the '209 patent nor the '785 patent requires use of a buffer, nor use of acetate buffer specifically.

318. Further, the specification emphasizes that the choice of buffer can affect stability, indicating to a POSA that the choice of buffer can impact whether a given formulation will achieve the claimed impurity levels.

319. There is no disclosure in the specification evidencing that the inventors were in possession of any one of the other numerous compositions falling within the scope of the '209 and '785 patents that achieve the claimed impurity levels, including without use of a buffer or with a buffer other than acetate buffer.

320. Additionally, the sole disclosure of a vasopressin composition that was formulated to a pH of 3.7 to 3.9 and, at certain time points during the stability study, obtained the claimed impurity levels did not, at the same time, achieve "0.1%" SEQ ID NO.: 3 as required by claim 3 of the '209 patent and claim 4 of the '785 patent.

I. All Asserted Claims Lack Adequate Enablement

1. '526 Patent

321. As set forth above regarding written description, the '526 patent specification contains no disclosure of any formulation with a pH of 3.8 that satisfies the degradation limitation of the asserted claim.

322. At most, the specification of the '526 patent teaches a POSA how to make a composition with a pH 3.8 and an acetate buffer. The scope of the '526 patent claim 13, however, covers far more embodiments than just those formulations with acetate buffer.

323. The '526 patent does not teach a POSA how to make and use the full scope of claimed formulations that achieve less than 1% degradation after storage for four weeks under refrigeration with any other type of buffer or without any

buffer. A POSA would need to engage in undue experimentation to determine how to prepare the full scope of formulations with different buffers at different concentrations or without a buffer that satisfy the degradation limitation and can be used in the recited method of treatment.

324. The inventors represented to the PTO that buffer selection, including concentration, and its effect on the stability of vasopressin formulations was unpredictable. Such unpredictability would have hindered a POSA's ability to practice the full scope of the invention as claimed and required additional undue experimentation.

325. Further, the specification emphasizes that the choice of buffer can affect stability, indicating to a POSA that the choice of buffer can impact whether a given formulation will achieve the claimed degradation level.

326. Par's expert also argues that peptide stability is unpredictable.

327. Par has further taken the position that a formulation with the recited amount of vasopressin, acetic acid, and water at pH 3.8 does not necessarily satisfy the percent degradation limitation of the Asserted Claims to argue that the claims are nonobvious. If that is the case, there is nothing else in the '526 patent specification that teaches a POSA how to prepare a formulation that exhibits the requisite level of degradation.

328. Instead, because Par requires for nonobviousness teaching beyond the formulation and pH to achieve the degradation limitation, a POSA would need to engage in undue experimentation to determine how to prepare the full scope of formulations that exhibit less than 1% degradation when stored for about four weeks at 2–8 °C.

329. In addition, because, according to Par, not all formulations that meet the vasopressin, acetic acid, water, and pH limitations of the asserted claim achieve less than 1% degradation when stored for about four weeks at 2–8 °C, there must be a significant number of inoperative embodiments. The existence of such inoperative embodiments further undermines the predictability of the claimed invention across its full scope.

2. '209 and '785 Patents

330. As noted above for written description, at most, the '209 and '785 patents teach a POSA how to make a composition with an acetate buffer that, at certain time points, satisfies the claims' impurity requirements.

331. The '209 and '785 patents do not teach a POSA how to make and use the full scope of claimed formulations that achieve the claimed impurity levels. A POSA would need to engage in undue experimentation to determine how to prepare the full scope of formulations with different buffers at different concentrations or

without a buffer that satisfy the impurities limitations and, for the '209 patent, can be used in the recited method of treatment.

332. The inventors represented to the PTO that buffer selection, including concentration, and its effect on the stability of vasopressin formulations was unpredictable. Such unpredictability hinders a POSA's ability to practice the invention as claimed and requires additional undue experimentation.

333. Further, the specification emphasizes that the choice of buffer can affect stability, indicating to a skilled artisan that the choice of buffer can impact whether a given formulation will achieve the claimed impurity levels.

334. Par's expert also argues that peptide stability is unpredictable.

335. Par has further taken the position that a vasopressin formulation with pH 3.7 to 3.9 does not necessarily satisfy the impurities limitations of the Asserted Claims to argue that the claims are nonobvious. If that is the case, there is nothing else in the patent specifications that teaches a POSA how to prepare a formulation with the requisite levels of impurities.

336. Instead, because Par requires for non-obviousness teaching beyond the formulation and pH to achieve the impurity levels, a POSA would need to engage in undue experimentation to determine how to prepare the full scope of formulations that achieve the claimed impurity levels.

337. In addition, because, according to Par, not all formulations that meet the composition limitations achieve the impurities limitations, there must be a significant number of defective embodiments. The existence of such defective embodiments requires undue experimentation by a POSA to find those limited formulations that can achieve the asserted impurities limitations.

J. All Asserted Claims Are Indefinite

1. Less Than [X]% Degradation After Storage at 2–8°C for About Four Weeks

338. Claim 13 of the '526 patent is indefinite with respect to the following limitation: “less than [X]% degradation after storage at 2-8° C. for about four weeks.”

339. Neither the specification nor the prosecution history inform a skilled artisan, with reasonable certainty, as to whether percent degradation refers to loss of vasopressin or formation of impurities.

340. Neither the specification nor the prosecution history inform a skilled artisan, with reasonable certainty, as to whether percent degradation is an absolute or relative measurement.

341. Neither the specification nor the prosecution history inform a skilled, with reasonable certainty, as to the proper time frame for measuring percent degradation.

2. When to Measure pH

342. Each of the Asserted Patents are indefinite with respect to when to measure pH of the claimed compositions.

343. Neither the specification nor the prosecution history inform a skilled artisan, with reasonable certainty, as to whether pH is measured at the time of manufacturing, at the time of administration, or at any time during stability.

344. Additionally, with respect to claim 13 of the '526 patent, neither the specification nor the prosecution history inform a skilled artisan, with reasonable certainty, as to whether the claimed composition must first be “provided” with a pH of 3.8 prior to storage at 2–8°C for at least four weeks.

V. THIS CASE IS EXCEPTIONAL AND EAGLE SHOULD BE AWARDED ITS REASONABLE ATTORNEY FEES

A. Par Lacked a Reasonable Basis to Bring and Maintain this Suit Against Eagle

345. Well before Par filed its Complaint against Eagle asserting the Patents-in-Suit, Par was on notice that Eagle’s ANDA product and its use upon approval would not infringe any of the Asserted Claims. Eagle informed Par in its Paragraph IV Notice Letter of April 16, 2018, that Eagle’s ANDA product did not have a pH between 3.7 and 3.9, or 3.8, and, therefore, did not infringe the Patents-in-Suit. Subsequently, but before Par filed its Complaint, Eagle produced the relevant portions of its ANDA to Par, clearly providing the pH [REDACTED]

for its ANDA product and thus informing Par that Eagle's ANDA product does not satisfy the composition limitations of the Asserted Claims.

346. In addition, Par knew, through Eagle's pre-suit production of its ANDA, [REDACTED] that any allegation of infringement is effectively an admission that the Asserted Claims are invalid.

347. Before this suit was filed, Par knew that the '239 patent claims had only issued due to the successful disqualification of the April 2014 Vasostrict® Label as prior art during prosecution through the unmistakably false Kannan and Bonomi-Huvala Declarations. Par also knew that the '239 patent claims covered its prior art Original Vasostrict® product, and were therefore invalid. Given the unmistakable falsity of the Declarations submitted to secure the '239 patent claims and the clear invalidity of those claims, Par did not have a reasonable basis to assert the '239 patent in its Complaint.

348. Par specifically relied on its assertion of the '239 patent to avoid summary judgment briefing in this action. Par maintained that assertion for over a year, before dropping it from the case on the day it was required to provide discovery that would have exposed the inequitable conduct, unilaterally evading that discovery.

349. Because the '239 patent is a parent of the Patents-in-Suit and shares named inventors and many claim requirements, Par did not have a reasonable basis to assert the Patents-in-Suit as they are unenforceable through the doctrine of infectious unenforceability.

350. Par further lacked a reasonable basis to assert the Buffer Patents in its Complaint, which have since been dismissed,⁹ as Eagle, again, explained prior to this lawsuit that its ANDA product did not satisfy the pH and acetate buffer limitations of those claims. During the *Markman* phase of the case, Par resisted a claim construction that would have excluded acetic acid from the scope of the “acetate buffer” term in accordance with its clear disclaimer during prosecution and maintained the Buffer Patents in the case even though, as confirmed by the named inventors during their depositions, it knew that acetic acid alone did not act as an acetate buffer in its Original Vasostrict® product [REDACTED]

[REDACTED]

⁹ Par continued to assert the Buffer Patents despite lacking a reasonable basis to allege that Eagle’s ANDA product [REDACTED]
[REDACTED]
[REDACTED] to practice the method of the '223 patent. Despite lacking any reasonable basis to do so, Par continued to assert infringement of those patents until the very end of discovery and only after multiple named inventors confirmed that Eagle’s ANDA product could not infringe those patents.

351. Nevertheless, Par proceeded to file this lawsuit and assert the Patents-in-Suit, as well as the '239 patent and Buffer Patents, against Eagle despite having knowledge that Eagle's ANDA product did not and, if approved, could not have a pH within that of the Asserted Claims, and did not have [REDACTED]

352. Following its Complaint, Par did not, at any juncture, have a reasonable basis to maintain this lawsuit against Eagle. Even after the completion of fact and expert discovery, Par has still not set forth any reasonable basis to maintain this litigation. Eagle's ANDA specification has not changed; [REDACTED]
[REDACTED] Instead, Par relies solely on [REDACTED]
[REDACTED]
[REDACTED] under settled Federal Circuit law, is not cognizable in view of the ANDA specification and, regardless, insufficient to satisfy Par's burden.

353. Eagle has also [REDACTED]
[REDACTED]
[REDACTED] Par's expert has admitted he has no evidence that products made pursuant to [REDACTED]—as would occur after approval—will ever have a pH within the Asserted Claims.

354. In a misguided attempt to plug the glaring gaps in its evidence, after the close of expert discovery, Par submitted—without Eagle's consent or leave of the Court—untimely supplemental expert reports from its expert Dr. Kirsch purporting

to identify new theories, based on linear regression and prediction intervals, as to why the pH of Eagle's ANDA Product is likely to [REDACTED] into the claimed range.¹⁰ But after Eagle and its experts expended significant resources responding to those reports—including pointing out that Dr. Kirsch's theories confirmed Eagle's [REDACTED]

[REDACTED], and that the Asserted Claims are invalid over the prior art applying Dr. Kirsch's new theories—Par withdrew those reports to try to avoid their consequences on non-infringement and invalidity.

355. Par was also aware throughout this litigation that the '239 patent was obtained through inequitable conduct in the form of the false Kannan and Bonomi-Huvala Declarations and the representations that relied on them. Par, though, continued to maintain its allegations with respect to the '239 patent up until the deadline to provide discovery regarding the conception and reduction to practice of that patent and its prosecution, on the eve of inventor depositions.

356. After Par ceased asserting the '239 patent, the inventors of that patent, including Vinayagam Kannan and Matthew Kenney, confirmed the Kannan and Bonomi-Huvala Declarations, as well as the representations based thereupon, were

¹⁰ Par also produced sales data for prior art Pitressin [REDACTED]
[REDACTED]
[REDACTED]

false. In fact, all inventors confirmed that they did not contribute to the subject matter set forth in those Declarations and Par's 30(b)(6) witness testified that Par lacked any evidence that any particular individual was responsible for the subject matter set forth in those Declarations.

357. Thus, even if Par did not believe that the '239 patent was obtained through fraud at the outset of this lawsuit, it clearly learned of the underlying inequitable conduct during this litigation but continued to assert the '239 patent until near the end of discovery. Par further continued to assert the Patents-in-Suit despite the fact that they are unenforceable under the doctrine of infectious unenforceability based on inequitable conduct during prosecution of the '239 patent.

358. Eagle also pleaded, in detail, the unenforceability of the '239 patent and how the doctrine of infectious unenforceability affects the Patents-in-Suit in its October 28, 2019 Amended Answer and Counterclaim. Par has, however, maintained this suit thereafter.

359. Because Par lacked a reasonable basis to bring and maintain this suit, this case is exceptional and Eagle should be awarded its reasonable attorney fees.

B. Par Brought this Suit in Bad Faith

360. Par brought this suit in bad faith in order to maintain its monopoly on the supply of vasopressin.

361. Par pursued an NDA for vasopressin pursuant to the FDA's Unapproved Drugs Initiative ("UDI").

362. Under the UDI, the FDA encouraged manufacturers to submit NDAs for unapproved grandfathered products that had been marketed since before the advent of the formal FDA approval process. Such grandfathered products may be made and sold without FDA approval.

363. In exchange for filing an NDA and obtaining formal FDA approval, manufacturers would receive a brief period of de facto exclusivity because competing unapproved products were to be removed from the market and made to pursue their own regulatory approvals. No special regulatory exclusivities were attached to NDAs submitted and approved per the UDI.

364. Par has had a monopoly on the supply of vasopressin since December 2014, when, following the approval of Par's NDA for its unapproved vasopressin product, the FDA removed all competing vasopressin products from the market.

365. Par obtained and asserted the Patents-in-Suit in order to extend its de facto exclusivity with a patent monopoly and prevent competing vasopressin products from returning to the market.

366. During that time, Par has increased the price of vasopressin from approximately five dollars per vial to well over one hundred thirty dollars per vial. Because vasopressin is a life-saving drug used to treat refractory cases of lethal

conditions, hospitals have continued to purchase and use vasopressin notwithstanding Par's monopoly pricing.

367. Although Par lacked a reasonable basis to assert the Patents-in-Suit, as well as the those patents that have been dismissed, against Eagle, it did so in order to obtain a thirty month stay of approval of Eagle's ANDA under the Food, Drug, and Cosmetic Act. If Par did not bring this baseless litigation against Eagle, Eagle's ANDA would have been eligible for approval as soon the FDA deemed appropriate. Eagle would be free to launch as soon as it received such approval. Instead, Eagle's ANDA is ineligible for final approval until Eagle either prevails in this Court or October 2020.

368. Thus, by filing and maintaining this baseless suit, Par was able to guarantee that its monopoly would not be broken by Eagle for more than two additional years. During that time, Par has continued to increase the price of vasopressin and enjoy monopoly profits.

369. On November 25, 2020, the FDA announced that it was terminating the UDI because it had determined that, under this initiative, the prices of previously unapproved drugs had increased significantly. Termination of the Food and Drug Administration's Unapproved Drugs Initiative, 85 Fed. Reg. 75,331, 75,332 (Nov. 25, 2020) ("After the UDI began, reports emerged that Americans were paying

significantly more for prescription drugs approved by FDA through the UDI than they had paid previously.”).

370. In its announcement regarding the termination of the UDI, the FDA cited the pricing of vasopressin following the approval of Par’s NDA in support of its decision. Termination of the Food and Drug Administration’s Unapproved Drugs Initiative, 85 Fed. Reg. 75,331, 75,332 (Nov. 25, 2020) (“Another report asserted that ‘[t]hanks at least partially to the FDA program, the price of vasopressin . . . has risen 10-fold’” (alterations in original) (citation omitted)).

371. Because this suit was brought in bad faith, this case is exceptional and Eagle should be awarded its reasonable attorney fees.

C. Par’s Engaged in Inequitable Conduct to Procure the Patents-in-Suit

372. As set forth above, Par obtained the Patents-in-Suit through inequitable conduct and, in addition, the Patents-in-Suit are tainted and unenforceable on account of the inequitable conduct that occurred in the parent ’239 patent prosecution.

373. Because Par engaged in inequitable conduct, this case is exceptional and Eagle should be awarded its reasonable attorney fees.

D. Response to Par's Allegations in Paragraphs 271–279 of Par's Statement of Contested Facts

374. Par's allegations concerning the parties' disputes during fact discovery are not germane to issues to be decided at trial. Further, Eagle disagrees with Par's characterizations of the parties' discovery disputes for the following reasons:

- An unredacted copy of Eagle's ANDA, including FDA correspondence received and submitted to that point, was provided nearly five weeks prior to service of Par's initial infringement contentions in December 2018, in accordance with the Scheduling Order.
- Eagle did not avoid its discovery obligations or withhold any evidence of infringement. To the contrary, Eagle provided all available stability data for its ANDA Product, FDA correspondence, and ANDA submissions well-before the end of fact discovery, including prior to Rule 30(b)(6) depositions of Eagle witnesses designated on topics related to stability data, FDA correspondence, and Eagle's ANDA. To the extent any additional stability data were generated after the end of fact discovery, Eagle has continued to supplement its production with the additional stability data.
- Eagle's delay in producing the [REDACTED] [REDACTED] was inadvertent, caused no prejudice to Par, and has no bearing on any issues in this case. Eagle's counsel produced [REDACTED]

█████ immediately upon learning of its existence. Eagle subsequently produced ██████████ the day after it submitted the response to the FDA. Both ██████ and Eagle's response thereto were produced before the end of fact discovery, including prior to Rule 30(b)(6) depositions of Eagle witnesses designated on topics related to FDA correspondence and Eagle's ANDA, well before Par's final infringement contentions and opening expert reports were served.

- The only evidence Par and its experts rely on for alleged infringement—████████████████████—was produced before Eagle produced ██████ Neither Par nor Par's experts have relied on ██████ itself to support Par's allegations of infringement or for any other purpose, confirming that it suffered no prejudice from the timing of ██████ production, and that ██████ is not responsible for Par's baseless infringement claims.

VI. PAR IS NOT ENTITLED TO INJUNCTIVE OR MONETARY RELIEF

375. Par cannot prove that it is entitled to a judgment against Eagle for infringement of any Asserted Claim.

376. Par cannot prove that it is entitled to any relief because Eagle does not infringe any valid, enforceable claim of the Patents-in-Suit.

377. Par cannot prove that it is entitled to injunctive relief.

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378. Par cannot prove that it suffered irreparable injury or harm.

379. Par cannot prove that the legal remedies available to it are inadequate to compensate any alleged injury or harm.

380. Par cannot prove that the balance of hardships favors an injunction.

381. Par cannot prove that an injunction is in the public interest.

382. Par cannot prove that it is entitled to damages or other monetary relief.

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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

<p>PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC and ENDO PAR INNOVATION COMPANY, LLC,</p> <p>Plaintiffs,</p> <p>v.</p> <p>EAGLE PHARMACEUTICALS INC.,</p> <p>Defendant.</p>	<p>C.A. No. 18-cv-823-CFC</p> <p>[REDACTED]</p>
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**PLAINTIFFS' STATEMENT OF CONTESTED ISSUES OF LAW
THAT REMAIN TO BE LITIGATED**

Pursuant to Local Rule 16.3(c)(5), Plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC (collectively “Par”) submit the following issues of law that remain to be litigated. The following statements are not exhaustive, and Par reserves the right to prove any matters identified in its pleadings, interrogatory responses, and/or expert reports. Par reserves the right to modify or amend this Statement to the extent necessary to reflect any future rulings by the Court, and to supplement or amend this Statement to fairly respond to any new issues that Defendant may raise. To the extent Par’s statement of the issues of fact that remain to be litigated, which is submitted as

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Exhibit 2 hereto, contains issues of law, those issues are incorporated herein by reference. Moreover, if any issue of law identified below should properly be considered an issue of fact, then such statement should be considered to be part of Par's statement of issues of fact that remain to be litigated. Plaintiffs' Statement of Intended Proofs is submitted as **Exhibit 13** hereto.

Further, Par's identification of the issues that remain to be litigated on issues where Eagle bears the burden of proof is based on its understanding of the arguments that Eagle has put forth to date. To the extent Eagle intends or attempts to introduce different or additional legal arguments to meet their burden of proof, Par reserves its rights to contest those legal arguments, and to present any and all rebuttal evidence in response to those arguments, and will not be bound by this summary of remaining legal issues.

I. INFRINGEMENT

1. Whether Par has proven by a preponderance of the evidence that Eagle has infringed the Asserted Claims and would infringe those Claims if it were to make and sell its proposed ANDA product.

2. Pursuant to the Hatch-Waxman Act, it is an act of infringement to submit an Abbreviated New Drug Application ("ANDA") to the United States Food and Drug Administration ("FDA") seeking FDA approval to commercially

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make and sell a patented drug product. *See, e.g.*, 35 U.S.C. § 271(e)(2); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 156970 (Fed. Cir. 1997).

3. “Although no traditional patent infringement has occurred until a patented product is made, used, or sold, under the Hatch–Waxman framework, the filing of an ANDA itself constitutes a technical infringement for jurisdictional purposes.” *Sunovion Pharms., Inc. v. Teva Pharms. USA, Inc.*, 731 F.3d 1271, 1278 (Fed. Cir. 2013).

4. In considering the issue of infringement under § 271(e)(2), the court may consider the ANDA, materials submitted by the generic applicant to the FDA, and other pertinent evidence provided by the parties. *Glaxo*, 110 F.3d at 1570.

5. While the filing of an ANDA itself constitutes a technical infringement for jurisdictional purposes, the “ultimate infringement question is determined by traditional patent law principles and, if a product that an ANDA applicant is asking the FDA to approve for sale falls within the scope of an issued patent, a judgment of infringement must necessarily ensue.” *Sunovion*, 731 F.3d at 1280.

6. “What [the generic manufacturer] has asked the FDA to approve as a regulatory matter is the subject matter that determines whether infringement will occur.” *Id.* at 1279. Thus, even if the generic “either tells the court that its manufacturing guidelines will keep it outside the scope of the claims or has even

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filed a declaration in the court stating that it will stay outside the scope of the claims,” the generic is liable for infringement if “it has asked the FDA to approve, and hopes to receive from the FDA, approval to market a product within the scope of the issued claims.” *Id.*

7. Thus, for example, in *Sunovion*, the district court granted judgment of non-infringement in favor of the generic manufacturer, Dr. Reddy’s, based on evidence that by following its internal manufacturing guidelines, the product Dr. Reddy’s would make and sell would be outside the scope of the claims. *Id.* at 1274-75, 1278. The Federal Circuit reversed, because notwithstanding Dr. Reddy’s “guarantee” that its internal manufacturing guidelines would result in a non-infringing product, the ANDA specification for the product, if approved by the FDA, would allow it to sell a product that would infringe. *Id.* at 1279.

8. The Federal Circuit noted that “[i]f it had no intent to infringe, Reddy should not have requested, or should not accept, approval to market a product within the scope of the claim.” *Id.* It further found that “[t]he possibility that Sunovion could later test any of Reddy’s commercially available generic eszopiclone products, when approved, and bring an infringement action under § 271(a), as Reddy argues, unnecessarily defers resolution of the infringement issue that the Hatch–Waxman framework was intended to address earlier, generally before ANDA approval.” *Id.* The Federal Circuit further pointed out that “it would

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be practically impossible for Sunovion, the FDA, or any court to monitor Reddy's compliance," so as to determine on an ongoing basis whether Dr. Reddy's was complying with its internal manufacturing guidelines and pledge of non-infringement. *Id.*

9. Moreover, a patentee can succeed in a Hatch-Waxman Act ANDA case if it can demonstrate, with relevant evidence, that the likely to-be-marketed ANDA product can be expected to infringe, even if strict conformity with the product specifications would indicate otherwise. *See, e.g., Tyco Healthcare Grp. LP v. Mutual Pharm. Co., Inc.*, 762 F.3d 1338, 1344 (Fed. Cir. 2014) (noting that the infringement inquiry "must be based on all of the relevant evidence *including* the ANDA" and that patentee may prove infringement by a generic defendant if it "has evidence that the as-marketed commercial ANDA product will infringe") (quoting *Glaxo*, 110 F.3d at 1568) (emphasis in original); *Bayer AG. V. Biovail Corp.*, 279 F.3d 1340, 1346-47 (Fed. Cir. 2002) ("Even assuming Elan strictly follows its 60 mg ANDA (presumably identical in relevant part to the 30 mg ANDA) in making a commercial tablet, Professor Antonietti's declaration raises a legitimate question as to whether Elan will likely make a 60 mg product that literally infringes Bayer's '466 patent upon approval of the ANDA").

10. "[W]hoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b).

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11. To prove inducement to infringe, the patentee must “establish[] that the defendant possessed specific intent to encourage another’s infringement.” *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006) (en banc in relevant part). Proof of intent can consist of evidence of active steps taken to encourage direct infringement such as advertising an infringing use or instructing how to engage in an infringing use. *See Vanda Pharms. Inc. v. West-Ward-Pharms. Int’l Ltd.*, 887 F.3d 1117, 1129 (Fed. Cir. 2018); *Takeda Pharms. U.S.A. Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015).

12. “While proof of intent is necessary, direct evidence is not required; rather, circumstantial evidence may suffice.” *DSU*, 471 F.3d at 1306; *see also Sanofi v. Watson Labs. Inc.*, 875 F.3d 636, 645 (Fed. Cir. 2017) (affirming “district court’s finding of inducement based on encouragement and inferred intent” based on defendant’s label providing “clear encouragement” to use the product in a manner that infringed the asserted claims).

13. In the Hatch-Waxman context, where the proposed label instructs users to perform the patented method, the proposed label may provide evidence of the ANDA applicant’s affirmative intent to induce infringement. *Vanda*, 887 F.3d at 1129. In particular, intent to induce infringement can be inferred where the language in the label would inevitably lead some consumer to practice the claimed method. *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010)

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(affirming judgment of induced infringement where the district court found that the generic “included instructions in its proposed label that will cause at least some users to infringe the asserted method claims.”).

14. Direct infringement of a method claim occurs where all steps of the claimed method are performed by or attributable to a single entity. *See Akamai Techs., Inc. v. Limelight Nets., Inc.*, 797 F.3d 1020, 1022 (Fed. Cir. 2015). Where more than one actor is involved in the performance of the steps of the claimed method, the court must determine whether the acts of one are attributable to the other, such that a single entity is responsible for the infringement. *Id.* To do so, the patentee may show either that a single entity “directs or controls others’ performance,” or that separate actors “form a joint enterprise.” *Id.*

15. “To determine if a single entity directs or controls the acts of another, we continue to consider general principles of vicarious liability.” *Id.* at 1022-23 (citing *BMC Resources, Inc. v. Paymentech, L.P.*, 498 F.3d 1373, at 1378-79 (Fed. Cir. 2007)). Thus, for example, an actor is liable for infringement under § 271(a) “if it acts through an agent (applying traditional agency principles) or contracts with another to perform one or more steps of a claimed method.” *Id.*

16. “Alternatively, where two or more actors form a joint enterprise, all can be charged to the acts of the other, rendering each liable for the steps performed by the other as if each is a single actor.” *Akamai*, 797 F.3d at 1023.

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17. The Federal Circuit utilizes the test set forth in the Restatement (Second) of Torts § 491 to determine the existence of a joint enterprise. *Id.* The test requires proof of (1) an agreement, express or implied, among the members of the group, (2) a common purpose to be carried out by the group, (3) a community of pecuniary interest in that purpose, among the members; and (4) an equal right to a voice in the direction of the enterprise, which gives an equal right of control. *Id.*

18. With respect to the fourth element, the patentee need only show that the actors both controlled their *shared* enterprise. *See Shure, Inc. v. ClearOne, Inc.*, No. 17-cv-3078 (EEC), 2018 WL 1371170, at *9 (N.D. Ill. Mar. 16, 2018) (finding the “equal right” prong “met by the fact that the parties had to work together to undertake the joint project”); *Reagent Chem. & Research, Inc. v. Eurotarget S.R.L.*, No. 1:16-cv-395, 2016 WL 8200435, at *6 (M.D. Pa. May 23, 2016) (noting that an “equal right to a voice in the direction of the enterprise” includes merely that the actors “may control whether and when the [infringing] activity takes place”). This fourth element can be proven by the fact that the parties worked together to undertake the joint project of promoting their common goal. *Shure*, 2018 WL 1371170, at *9; *Reagent Chem.*, 2016 WL 8200435, at *6.

19. Eagle’s commercial manufacture, use, sale, importation, and/or offer for sale of its infringing products would indirectly infringe the Asserted Claims of

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the Asserted Patents by inducing others to use its infringing ANDA products and/or inducing others to perform all of the steps of the claimed methods.

20. In particular, if Eagle's ANDA products are used and administered as intended and instructed on the proposed labels for the products, hospitals and/or medical professionals working within the hospital (such as doctors, nurses, physicians' assistants, pharmacists (including clinical pharmacists) and pharmacy staff), acting alone or in combination with one another, would perform each and every step of the methods of treatment recited in the Asserted Claims of the '209 and '526 patents and use the claimed formulations of the '785 patent.

21. To the extent the steps of the claimed methods would be performed by more than one such person, all of the steps are attributable to a single entity—*e.g.*, hospitals that hire and/or contract with, and are vicariously liable for the actions of, the medical professionals that will store and administer Eagle's ANDA products—that directly infringes the Asserted Claims.

22. Eagle has knowledge of the Asserted Patents, and by virtue of its proposed product label, package insert, and other conduct, it would actively and intentionally induce such infringement.

II. CLAIM CONSTRUCTION

23. The infringement analysis involves two steps. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370

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(1996). The first step is to define disputed terms of the patent consistent with how those terms would be understood by a person of ordinary skill in the art. *Id.*; *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc).

24. “[T]he words of a claim are generally given their ordinary and customary meaning,” which is “the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention.” *Phillips*, 415 F.3d at 1312–13 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)).

25. The ordinary meaning may be determined by reviewing various sources, such as the claims themselves, the specification, the prosecution history, dictionaries, and any other relevant evidence. *See Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002).

26. This Court construed the disputed claim terms in a Memorandum Opinion dated July 1, 2019 (D.I. 71).

27. The second step of the infringement inquiry is to determine whether the accused product infringes the patent, which is done by comparing the accused product with the properly construed claims. *Markman*, 52 F.3d at 976.

III. VALIDITY

28. Whether Eagle has proven by clear and convincing evidence that any of the Asserted Claims are invalid.

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29. The Asserted Claims are presumed to be valid, and the burden of proving invalidity of each claim rests with Eagle. 35 U.S.C. § 282. The presumption that an issued patent claim is valid requires that an invalidity defense or counterclaim be proven by clear and convincing evidence. *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2242 (2011). The presumption of validity and corresponding burden of proof in overcoming that presumption applies to each patent claim independently. *See Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1050 (Fed. Cir. 1988); *Carroll Touch, Inc. v. Electro Mechanical Sys., Inc.*, 15 F.3d 1573, 1581 (Fed. Cir. 1993).

30. Par's identification of the issues of validity that remain to be litigated is based on its understanding of the arguments that Eagle is likely to make in attempting to establish invalidity, given the pleadings and discovery in the action to date. To the extent Eagle intends or attempts to introduce different or additional legal arguments to meet their burden of proof, Par reserves its rights to contest those legal arguments, and to present any and all rebuttal evidence in response to those arguments, and will not be bound by this summary of remaining legal issues.

A. Anticipation

31. Whether Eagle has proven by clear and convincing evidence that any Asserted Claim is invalid as anticipated by the prior art.

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32. “A person shall be entitled to a patent unless the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.” 35 U.S.C. § 102(a)(1).

33. Anticipation is a question of fact, subject to the Court’s application of the proper legal standards in making that factual determination. *See Microsoft Corp. v. Biscotti, Inc.*, 878 F.3d 1052, 1067-68 (Fed. Cir. 2017).

34. “In order to anticipate the claimed invention, a prior art reference must ‘disclose all elements of the claim within the four corners of the document,’ and it must ‘disclose those elements ‘arranged as in the claim.’” *Id.* at 1063 (quoting *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008)); 35 U.S.C. § 102.

35. In order to prove inherent anticipation, the patent challenger must prove by clear and convincing evidence that the missing element or elements are necessarily present in the allegedly anticipating disclosure. *See Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991); *see also Transclean Corp. v. Bridgewood Servs., Inc.*, 290 F.3d 1364, 1373 (Fed. Cir. 2002). Inherency “may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not

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sufficient.” *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (quoting *Continental Can*, 948 F.2d at 1269).

36. To prove anticipation by a prior art product, “the party with the burden of proof must show that the subject of the barring activity met each of the limitations of the claim, and thus was an embodiment of the claimed invention.” *See Juicy Whip, Inc. v. Orange Bang, Inc.*, 292 F.3d 728, 737 (Fed Cir. 2002) (internal quotations omitted) (reversing a jury verdict of anticipation by a prior art device because the record lacked evidence “regarding at least one limitation of each asserted claim”).

37. “In order to anticipate a claimed invention, a prior art reference must enable one of ordinary skill in the art to make the invention without undue experimentation.” *Impax Labs., Inc. v. Aventis Pharms., Inc.*, 545 F.3d 1312, 1314 (Fed. Cir. 2008) (citing *Finisar Corp. v. DirecTV Grp., Inc.*, 523 F.3d 1323, 1336 (Fed. Cir. 2008)).

B. Obviousness

38. Whether Eagle has proven by clear and convincing evidence that any Asserted Claim is invalid as obvious in view of the prior art to a person of ordinary skill in the art at the time of the claimed inventions (“POSA”).

39. Whether the definition of a POSA in this case is as follows:

A person with a Master’s, Pharm.D., or Ph.D. in the field of pharmaceutical sciences or a related discipline and several years of

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experience in the development of pharmaceutical dosage forms. The amount of experience would vary in relation to the level of formal education and depth of experience with pharmaceutical dosage development. A POSA may also have less formal education and a greater amount of experience. Further, a POSA would have had access to and would have working collaboration with persons having several years of experience in the formulation of drug products as well as other professions in the drug development field, such as pharmacologists, chemists, biologists, or clinicians.

40. Obviousness is a question of law that is based on underlying issues of fact. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 427 (2007).

41. To prove that the asserted claims are obvious, Eagle must prove by clear and convincing evidence that the differences between the claimed subject matter and the prior art are such that the invention would have been obvious to a hypothetical person having ordinary skill in the art at the time of invention. 35 U.S.C. § 103; *Microsoft*, 131 S. Ct. at 2242.

42. To determine obviousness, the Court must consider: (i) the scope and content of the prior art; (ii) the differences between the prior art and the claims at issue; (iii) the level of ordinary skill in the pertinent art; and (iv) objective or secondary considerations of nonobviousness, if present. *See Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966); *In re Rouffet*, 149 F.3d 1350, 1355 (Fed. Cir. 1998).

43. Even if the prior art discloses all the elements of a claim, the claim is only obvious if the patent challenger proves by clear and convincing evidence that

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a person of ordinary skill in the art would be motivated to combine the elements and would have a reasonable expectation that the combination would successfully result in the claimed invention. *Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1364 (Fed. Cir. 2011); *Procter & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 994 (Fed. Cir. 2009).

44. “[O]bviousness must be judged from the knowledge of one skilled in the art at the time of invention.” *Genetics Inst., LLC v. Novartis Vaccines & Diagnostics, Inc.*, 655 F.3d 1291, 1318 n.6 (Fed. Cir. 2011). Only art that meets the requirements of the relevant subsections of 35 U.S.C § 102 qualifies as prior art for an obviousness analysis under § 103. *See, e.g., Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1568 (Fed. Cir. 1987).

45. “Patentability shall not be negated by the manner in which the invention was made.” 35 U.S.C. § 103. A court cannot rely on an inventor’s own efforts to find obviousness, but it can consider an inventor’s testimony regarding how the invention was made in making a finding of nonobviousness. *E.g., Life Techs., Inc. v. Clontech Labs., Inc.*, 224 F.3d 1320, 1325 (Fed. Cir. 2000); *Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F.3d 1280, 1296 (Fed. Cir. 2012).

46. A defendant’s “burden [to prove invalidity by clear and convincing evidence] is especially difficult when the prior art was before the PTO examiner

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during prosecution of the application.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1467 (Fed. Cir. 1990). In that situation:

[The party asserting invalidity] has the added burden of overcoming the deference that is due to a qualified government agency presumed to have properly done its job, which includes one or more examiners who are assumed to have some expertise in interpreting the references and to be familiar from their work with the level of skill in the art and whose duty it is to issue only valid patents.

Am. Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1359 (Fed. Cir. 1984), *abrogated on other grounds by Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011).

47. The claimed invention must be viewed “in the state of the art that existed at the time the invention was made.” *Sensonics Inc. v. Aerosonic Corp.*, 81 F.3d 1566, 1570 (Fed. Cir. 1996).

48. The scope and content of the prior art must be considered as a whole. *See In re Wesslau*, 353 F.2d 238, 241 (C.C.P.A. 1965) (“It is impermissible . . . to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art.”); *see also In re Kuderna*, 426 F.2d 385, 389 (C.C.P.A. 1970) (“We must approach the issue of patentability in terms of what would have been obvious to one of ordinary skill in the art at the time the invention was made in view of the sum of all the relevant

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teachings in the art, not in view of first one and then another of the isolated teachings in the art.”).

49. “[S]ome kind of motivation must be shown from some source, so that the [fact-finder] can understand why a person of ordinary skill would have thought of either combining two or more references or modifying one to achieve the patented method.” *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1374 (Fed. Cir. 2008).

50. “[W]hen the prior art as a whole teaches away from combining certain known elements” by discouraging a person of ordinary skill in the art from following the path set out in the prior art or by leading the skilled artisan in a direction divergent from the path that was taken by the inventors of the claimed invention, “a successful means of combining [the known elements] is more likely to be nonobvious.” *KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007); *Depuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1327 (Fed. Cir. 2009). “[A] reference that ‘teaches away’ from a given combination may negate a motivation to modify the prior art to meet the claimed invention.” *Ormco Corp. v. AlignTech., Inc.*, 463 F.3d 1299, 1308 (Fed. Cir. 2006). “An inference of nonobviousness is especially strong where the prior art’s teachings undermine the very reason being proffered as to why a person of ordinary skill would have combined the known elements.” *Depuy Spine*, 567 F.3d at 1326.

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51. An invention claimed in a patent is not obvious if it is a solution to a problem which does not have a finite number of identified and predictable solutions or if the identified solution was not reasonably predictable. *KSR*, 550 U.S. at 421.

52. An invention claimed in a patent is not obvious if the prior art gives only general guidance as to the particular form of the claimed invention or how to achieve the invention. *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1073 (Fed. Cir. 2012). For “a patent challenger to establish obviousness, it is insufficient to allege a general motivation to discover an undefined solution that could take many possible forms.” *In re Armodafinil*, 939 F. Supp. 2d 456, 500, 502 (D. Del. 2002) (internal citations omitted); *see also In re Cyclobenzaprine*, 676 F.3d at 1072 (“Evidence of obviousness, especially when that evidence is proffered in support of an ‘obvious-to-try’ theory, is insufficient unless it indicates that the possible options skilled artisans would have encountered were ‘finite,’ ‘small,’ or ‘easily traversed,’ and that skilled artisans would have had a reason to select the route that produced the claimed invention.” (quoting *Ortho McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1364 (Fed. Cir. 2008))).

53. Hindsight must be avoided in the obviousness analysis. *KSR*, 550 U.S. at 421. “[T]he great challenge of the obviousness judgment is proceeding

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without any hint of hindsight.” *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 655 F.3d 1364, 1375 (Fed. Cir. 2011). When fact-finders fall prey to a hindsight-driven obviousness analysis, they often find motivation and a reasonable expectation of success where none existed at the time of the invention. *See, e.g., Ortho-McNeil*, 520 F.3d at 1364-65; *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 546 (Fed. Cir. 1998).

54. That which was unknown cannot have been obvious. *In re Newell*, 891 F.2d 899, 901-02 (Fed. Cir. 1989); *see also In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993) (“Such a retrospective view of inherency is not a substitute for some teaching or suggestion supporting an obviousness rejection.”).

55. To protect against the “distortion caused by hindsight bias,” there must be “a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” *KSR*, 550 U.S. at 418, 421.

56. An accused infringer must provide evidence that a “skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.” *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998).

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57. A patentee may argue objective indicia of non-obviousness, but is not obligated to do so, because objective indicia of non-obviousness are not a requirement of patentability. Therefore “[s]uch evidence, if present, would weigh in favor of non-obviousness, although the lack of such evidence does not weigh in favor of obviousness.” *Miles Labs., Inc. v. Shandon Inc.*, 997 F.2d 870, 878 (Fed. Cir. 1993); *see also Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 960 (Fed. Cir. 1986) (“[T]he absence of objective evidence does not preclude a holding of nonobviousness because such evidence is not a requirement for patentability [T]he absence of objective evidence is a neutral factor.” (internal quotation marks omitted)).

58. “[W]here there is a range disclosed in the prior art, and the claimed invention falls within that range, a relevant inquiry is whether there would have been a motivation to select the claimed composition from the prior art ranges. In those circumstances, the burden of production falls upon the patentee to come forward with evidence that (1) the prior art taught away from the claimed invention; (2) there were new and unexpected results relative to the prior art; or (3) there are other pertinent secondary considerations.” *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1304-05 (Fed. Cir. 2015) (internal citation and quotation marks omitted) (affirming district court’s holding that patentee successfully

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rebutted prima facie obviousness case where prior art disclosed range containing claimed drug concentration).

59. Where the issue of obviousness is based on overlapping ranges, “[o]ne way in which the patentee may rebut the presumption of obviousness is by showing that there is something special or critical about the claimed range.”

Genentech, Inc. v. Hospira, Inc., 946 F.3d 1333, 1341 (Fed. Cir. 2020) (internal citations omitted).

60. Courts have assessed criticality based on whether the claimed range is critical to the operability or functionality of the claimed invention. *See, e.g., Ineos USA LLC v. Berry Plastics Corp.*, 783 F.3d 865, 869-71 (Fed. Cir. 2015); *see also Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 999 (Fed. Cir. 2006).

61. The presumption of obviousness for overlapping ranges attaches only when “the range or value of a particular variable” is “**the difference** between the claimed invention and the prior art.” *Tris Pharma, Inc. v. Actavis Labs. Fl., Inc.*, No. 14-1309-CFC, 2020 WL 7028456, at *15 (D. Del. Nov. 30, 2020) (emphasis in original) (citing *Haynes Int’l, Inc. v. Jessop Steel Co.*, 8 F.3d 1573, 1577 n.3 (Fed. Cir. 1993)).

62. “[I]n order to render a claimed apparatus or method obvious, the prior art must enable one skilled in the art to make and use the apparatus or

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method.” *Endo Pharm. Inc. v. Amneal Pharm., LLC*, 224 F. Supp. 3d 368, 379-80 (D. Del. 2016) (quoting *In re Kumar*, 418 F.3d 1361, 1365 (Fed. Cir. 2005)).

C. Written Description

63. Whether Eagle has proven by clear and convincing evidence that any Asserted Claim is invalid as lacking an adequate written description.

64. The written description requirement is met if the specification and the existing knowledge in the art reasonably convey “to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1355 (Fed. Cir. 2010). For a patent claim to be held invalid for lack of written description, it must be proven by clear and convincing evidence that the patent fails to provide a POSA a basis “to recognize that the inventor invented what is claimed.” *Id.* at 1351. The test for reasonably conveying possession of an invention is a flexible one, “requir[ing] an objective inquiry into the four corners of the specification from the perspective of a [POSA].” *Id.*

65. A failure to “specifically mention a limitation that later appears in the claims is not a fatal one when one skilled in the art would recognize upon reading the specification that the new language reflects what the specification shows has been invented.” *All Dental Prodx, LLC v. Advantage Dental Prods., Inc.*, 309 F.3d 774, 779 (Fed. Cir. 2002).

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66. “Written description is a question of fact, judged from the perspective of one of ordinary skill in the art as of the relevant filing date.” *Immunex Corp. v. Sandoz Inc.*, 964 F.3d 1049, 1063 (Fed. Cir. 2020). “The [written description] requirement is applied in the context of the state of knowledge at the time of the invention.” *Zoltek Corp. v. U.S.*, 815 F.3d 1302, 1308 (Fed. Cir. 2016). The specification therefore “need not include information that is already known and available to the experienced public.” *Id.* (quoting *Space Sys./Loral, Inc. v. Lockheed Martin Corp.*, 405 F.3d 985, 987 (Fed. Cir. 2005)).

67. A specification implicitly satisfies the written description requirement if a POSA would find it “reasonably clear what the invention is and that the patent specification conveys that meaning.” *All Dental Prodx.*, 309 F.3d at 779. That is, the “reasonably conveys” standard does not require the disclosure and claims to match exactly. *Ariad Pharm.*, 598 F.3d at 1352 (“[T]he [written] description requirement does not demand any particular form of disclosure or that the specification recite the claimed invention *in haec verba*”).

68. Nor will a claim be invalidated simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language. *See Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575-76 (Fed. Cir. 1985) (holding that specification’s disclosure preferring a

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lower operating range, yet indicating no upper limit, combined with the industry knowledge at the time, was sufficient for a POSA to discern that higher ranges could be used).

69. A patent applicant need only convey, “with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” *Vas-Cath v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991) (emphasis in original).

70. The word “comprising” in a patent claim “suggests that there *may be* additional, unclaimed elements,” but such additional elements are not required. *See Technical Consumer Prods., Inc. v. Lighting Sci. Grp. Corp.*, 955 F.3d 16, 2020 WL 1696642, at *4 (Fed. Cir. 2020) (emphasis added) (citing *Crystal Semiconductor Corp. v. TriTech Microelecs. Int’l, Inc.*, 246 F.3d 1336, 1348 (Fed. Cir. 2001)).

71. Neither the written description nor enablement requirements of 35 U.S.C. § 112 require support for unclaimed elements. *See Lochner Techs., LLC v. Vizio, Inc.*, 567 F. App’x 931, 938-39 (Fed. Cir. 2014) (vacating summary judgment of invalidity for lack of written description and agreeing with patentee that “there is no precedent requiring a patentee to disclose or enable unclaimed elements”).

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72. “[A] patent claim is not necessarily invalid for lack of written description just because it is broader than the specific examples disclosed.” *Martek Biosci. Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1371 (Fed. Cir. 2009). Further, “[a]n applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention.” *Cordis Corp. v. Medtronic AVE, Inc.*, 339 F.3d 1352, 1365 (Fed. Cir. 2003) (quoting *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1344 (Fed. Cir. 2001)); *see also Lampi Corp. v. Am. Power Prods., Inc.*, 228 F.3d 1365, 1378 (Fed. Cir. 2000) (holding written description sufficient to support claims covering non-identical half-shells where patent drawings, the only cited written description support, only disclosed identical half-shells).

D. Enablement

73. Whether Eagle has proven by clear and convincing evidence that any Asserted Claim is invalid as not enabled.

74. A patent is enabled if a person of ordinary skill in the field could make and use the invention without having to perform undue experimentation. 35 U.S.C. § 112 ¶ 1; *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986).

75. Factors considered in determining whether experimentation is undue or excessive include: (1) the scope of the claimed invention; (2) the amount of

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guidance presented in the patent; (3) the amount of experimentation necessary; (4) the time and cost of any necessary experimentation; (5) how routine any necessary experimentation is in the applicable field; (6) whether the patent discloses specific working examples of the claimed invention; (7) the nature and predictability of the field; and (8) the level of ordinary skill in the field. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

76. Even a considerable amount of routine experimentation required to practice a claimed invention does not violate the enablement requirement. *Cephalon, Inc. v. Watson Pharms., Inc.*, 707 F.3d 1330, 1336 (Fed. Cir. 2013); *PPG Indus. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1565 (Fed. Cir. 1996).

77. “[T]he enablement requirement is met if the description enables any mode of making and using the invention.” *Invitrogen Corp. v. Clontech Laboratories Inc.*, 429 F.3d 1052, 1070-71 (Fed. Cir. 2005) (quoting *Johns Hopkins Univ. v. Cellpro, Inc.*, 152 F.3d 1342, 1361 (Fed. Cir. 1998)).

78. The specification preferably omits information that would already be known to a POSA. *Streck v. Res. & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1288 (Fed. Cir. 2012).

79. The enablement requirement “is limited to what is claimed. Section 112 requires enablement of only the claimed invention, not matter outside the

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claims.” *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 959 F.3d 1091, 1100 (Fed. Cir. 2020) (internal quotations omitted).

E. Definiteness

80. Whether Eagle has proven by clear and convincing evidence that any Asserted Claim is invalid as indefinite.

81. Section 112 “require[s] that a patent’s claims, viewed in light of the specification and prosecution history, inform[s] those skilled in the art about the scope of the invention with reasonable certainty. The definiteness requirement, so understood, mandates clarity, while recognizing that absolute precision is unattainable.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 910 (2014).

82. The presumption of validity afforded to patents means that “[a]ny fact critical to a holding on indefiniteness . . . must be proven by the challenger by clear and convincing evidence.” *Cox Commc’ns, Inc. v. Spring Commc’n Co. LP*, 838 F.3d 1224, 1228 (Fed. Cir. 2016) (alteration in original).

83. “[S]ome modicum of uncertainty is the price of ensuring the appropriate incentives for innovation . . . and patents are not addressed to lawyers, or even the public generally, but to those skilled in the relevant art.” *Nautilus*, 572 U.S. at 899 (internal citations omitted).

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84. For example, the Supreme Court “uph[eld] as definite a patent for an improvement to a paper-making machine, which provided that a wire be placed at a ‘high’ or ‘substantial elevation,’” as such terms would provide clear instructions to those skilled in the art the elevation required “for the machine to operate as specified.” *Id.* at 909 n.5 (citing *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45, 58, 65-66 (1923)).

IV. ENFORCEABILITY

85. Whether Eagle has met its burden of proving inequitable conduct during prosecution of the Asserted Patents by clear and convincing evidence. *Therasense, Inc. v. Becton, Dickinson and Co.*, 649 F.3d 1276, 1287-90 (Fed. Cir. 2011); *see also Outside the Box Innovations, LLC v. Travel Caddy, Inc.*, 695 F.3d 1285, 1290 (Fed. Cir. 2012).

86. To prove inequitable conduct, a challenger must demonstrate both that a person having a duty of candor and good faith to the PTO withheld or misrepresented information, or submitted false information, that was material to the examination of the patent application, and that this individual or individuals acted with the specific intent to deceive or mislead the PTO. *Therasense*, 649 F.3d at 1287-90, *Outside the Box*, 695 F.3d at 1290-92.

87. Materiality and intent to deceive are separate requirements that must each be proven by clear and convincing evidence. *Therasense*, 649 F.3d at 1287.

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If the accused infringer meets this burden, the district court must weigh the equities to determine whether the applicant's conduct before the PTO warrants rendering the entire patent unenforceable. *Id.*

88. In its seminal *en banc Therasense* decision, the Federal Circuit noted that the doctrine originated from a line of Supreme Court cases, each dealing with “particularly egregious misconduct, including perjury, the manufacture of false evidence, and the suppression of evidence.” *Id.* Subsequent lower court cases broadening the doctrine had “numerous unforeseen and unintended consequences,” including, “[m]ost prominently,” that the defense “has become a significant litigation strategy.” *Id.* at 1288. The Court decried the fact that litigants have flooded the courts with inequitable conduct allegations “routinely brought on ‘the slenderest grounds,’” finding that this “has plagued not only the courts but also the entire patent system.” *Id.* at 1289 (citation omitted).

89. In an effort to stem that tide, the *en banc* Court “now tightens the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public.” *Id.* at 1290.

90. “[T]he specific intent to deceive must be the single most reasonable inference able to be drawn from the evidence. . . . [W]hen there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found.” *Id.* at 1290-91 (internal citation omitted).

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91. There can be no inference of intent to deceive based solely on materiality. There must be a deliberate and conscious decision to withhold or misrepresent the information. *See id.* at 1290 (“A district court should not use a ‘sliding scale,’ where a weak showing of intent may be found sufficient based on a strong showing of materiality, and vice versa.”).

92. Moreover, “[a] finding that the misrepresentation or omission amounts to gross negligence or negligence under a ‘should have known’ standard does not satisfy this intent requirement.” *Id.* at 1290.

93. “[T]he materiality required to establish inequitable conduct is but-for materiality. When an applicant fails to disclose prior art to the PTO, that prior art is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art.” *Id.* at 1291. “But-for” materiality requires “proof that the patentee withheld or misrepresented information that, in the absence of the withholding or misrepresentation, would have prevented a patent claim from issuing.” *Ohio Willow Wood Co. v. Alps South, LLC*, 735 F.3d 1333, 1345 (Fed. Cir. 2013) (citing *Therasense*, 649 F.3d at 1291). This is a reflection of “basic fairness”—a patent should only be rendered unenforceable “in instances where the patentee’s misconduct resulted in the unfair benefit of receiving an unwarranted claim.” *Therasense*, 649 F.3d at 1292.

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94. *Therasense* recognizes a narrow exception to the requirement of “but for” materiality, which applies when “the patentee has engaged in affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit.” 649 F.3d at 1292. The exception is a reflection of the earlier Supreme Court cases, “which dealt with ‘deliberately planned and carefully executed scheme[s]’ to defraud not only the PTO and the courts.” *Id.* (citation omitted). It is intended to apply to “extraordinary circumstances” (*id.* at 1293), and as such, it is a narrow exception, reserved for “truly extreme misdeeds.” *Smith & Nephew, Inc. v. Interlace Med., Inc.*, 955 F. Supp. 2d 69, 73 (D. Mass. 2013); *see also Scanner Techs. Corp. v. ICOS Vision Sys. Corp. N.V.*, 528 F.3d 1365 (Fed. Cir. 2008) (reversing judgment of unenforceability based on allegedly false affidavit); *Golden Hour Data Sys., Inc. v. emsCharts, Inc.*, No. 2:06-CV-381-JRG, 2012 WL 3494366, at *12 (E.D. Tex. Aug. 15, 2012) (noting that this exception “is reserved for extreme behavior”).

95. “In a case involving nondisclosure of information, clear and convincing evidence must show that the applicant made a deliberate decision to withhold a known material reference.” *Therasense*, 649 F.3d at 1292 (citing *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1181 (Fed. Cir. 1995)).

96. “[I]nfectious unenforceability occurs when inequitable conduct renders unenforceable claims in a related application” having an immediate and

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necessary relation to the inequitable conduct. *Robocast, Inc. v. Apple Inc.*, 39 F. Supp. 3d 552, 570 (D. Del. 2014) (citing *Agfa Corp. v. Creo Prods., Inc.*, 451 F.3d 1366, 1379 (Fed. Cir. 2006); *Truth Hardware Corp. v. Ashland Prods., Inc.*, 2003 WL 22005839, at *1 (D. Del. Aug. 19, 2003)).

97. In order for a finding of inequitable conduct to render other patents in the same family unenforceable, there must be an “immediate and necessary relation” between the granting of subsequent patents and the misconduct alleged. *See Consol. Aluminum Corp. v. Foseco Intern. Ltd.*, 910 F.2d 804, 810-11 (Fed. Cir. 1990); *see also Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 243 (1933).

98. “The Federal Circuit has indicated that similar subject matter in related patents is not necessarily ‘infectious.’” *New Medium LLC v. Barco N.V.*, No. 05 C 5620, 2009 WL 10695784, at *2 (N.D. Ill. Mar. 18, 2009) (citing *Pharmacia Corp. v. Par Pharm., Inc.*, 417 F.3d 1369, 1373-75 (Fed. Cir. 2005) (holding that a finding of inequitable conduct did not infect a later patent defining a very similar invention and joined to the unenforceable patent by a terminal disclaimer)). “An ‘immediate and necessary relation’ requires a relation between ‘the inequitable conduct that occurred earlier in the chain’ of the issued patents and the ‘targeted claims of the ultimately-issued patent or patents sought to be enforced.’” *Baxalta Inc. v. Bayer Healthcare LLC*, 17-1316-RGA-SRF, 2020

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WL 5445375, at *10 (July 13, 2020) (citing *eSpeed, Inc. v. Brokertec USA, L.L.C.*, 417 F. Supp. 2d 580, 595 (D. Del. 2006)).

99. “[M]ere similarity in subject matter, mere citation to the unenforceable patent, and sharing a parent application are insufficient to invalidate a patent issued from a chain of applications in which inequitable conduct has been found as to an application without that chain.” *See Nilssen v. Osram Sylvania, Inc.*, 440 F. Supp. 2d 884, 900, 911 (N.D. Ill. 2006) (holding that inequitable conduct did not render other related patents sharing a common parent application unenforceable).

V. EXCEPTIONAL CASE

100. Whether this case is an exceptional case within the meaning of 35 U.S.C. § 285, such that Par is entitled to recover its attorneys’ fees and costs. *See Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 134 S. Ct. 1749, 1756 (2014).

EXHIBIT 5

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

PAR PHARMACEUTICAL, INC.,)	
PAR STERILE PRODUCTS, LLC, and)	
ENDO PAR INNOVATION)	
COMPANY, LLC,)	
)	C.A. No. 18-823-CFC
Plaintiffs,)	
)	
v.)	
)	
EAGLE PHARMACEUTICALS INC.,)	
)	
Defendant.)	

DEFENDANT'S STATEMENT OF ISSUES OF LAW
THAT REMAIN TO BE LITIGATED

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Pursuant to Local Rule 16.3(c)(5) and the Court’s Scheduling Order (D.I. 20, 148), Defendant Eagle Pharmaceuticals Inc. (“Eagle” or “Defendant”) respectfully submits the following issues of law that remain to be litigated and a citation of representative authorities relied upon. Eagle’s submission is based, in part, on its current understanding of the positions of the Plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC (collectively, “Par” or “Plaintiffs”) and the proceedings in this action to date.

In this action, Plaintiffs are currently asserting U.S. Patent No. 9,687,526 (“the ’526 patent”); U.S. Patent No. 9,744,209 (“the ’209 patent”); and U.S. Patent No. 9,750,785 (“the ’785 patent”) (collectively, the “Patents-in-Suit”).¹ Specifically, Plaintiffs are asserting claim 13 of the ’526 patent; claims 1, 3–5, and 7 of the ’209 patent; and claims 1, 4, 5, and 8 of the ’785 patent (the “Asserted Claims”).

Eagle reserves the right to amend or supplement this submission after considering Plaintiffs’ submissions, including amendments or supplementation made apparent in pre-trial proceedings, the trial itself, post-trial briefing, or otherwise.

¹ The Patents-in-Suit share two common inventors and a common chain of priority to U.S. Patent No. 9,744,239 (“the ’239 patent”), and therefore may be referred to as the “’239 family.” Each of these patents also claims priority to U.S. Application 14/610,499. Par has not disputed that the Patents-in-Suit are not entitled to priority dates earlier than their own filing dates, based on their claims of priority to the ’239 patent and ’499 application.

The following statements are not exhaustive, and Eagle reserves the right to prove any matters identified in its pleadings, invalidity contentions, interrogatory responses, and/or expert reports. In addition, the citation of authorities referenced in this document is not intended to be exhaustive. Eagle reserves the right to rely on additional authorities in support of its defenses and intended proofs. Eagle also reserves the right to rely upon the legal authorities cited by Plaintiffs in their corresponding exhibit.

By including an issue herein, Eagle does not assume the burden of proof or production with regard to that issue. For instance, Plaintiffs bear the burden of proof with respect to infringement.

To the extent this exhibit contains issues of fact, they are incorporated by reference into Defendant's Statement of Issues of Fact that Remain to be Litigated. To the extent Defendant's Statement of Issues of Fact That Remain to be Litigated contains issues of law, they are hereby incorporated into this exhibit.

SUBSTANTIVE ISSUES OF LAW REMAINING TO BE LITIGATED

I. ISSUES OF NONINFRINGEMENT REMAINING TO BE LITIGATED

1. Whether Plaintiffs have failed to carry their burden of proving by a preponderance of the evidence that any of the Asserted Claims of the Patents-in-Suit claims the drug, or use of the drug, that is the subject of Eagle's ANDA No. 211538, such that submission of that ANDA constituted infringement of any of the Asserted Claims of the Patents-in-Suit pursuant to 35 U.S.C. § 271(e)(2).

2. Whether Plaintiffs have failed to carry their burden of proving by a preponderance of the evidence that, if Eagle's ANDA No. 211538 were to be approved by the FDA, the manufacture, use, sale, offer for sale, or importation of the drug that is the subject of that ANDA would constitute direct infringement of any of the Asserted Claims of the Patents-in-Suit by Eagle.

3. Whether Plaintiffs have failed to carry their burden of proving by a preponderance of the evidence that, if Eagle's ANDA No. 211538 were to be approved by the FDA, the manufacture, use, sale, offer for sale, or importation of the drug that is the subject of that ANDA would constitute direct infringement of any of the Asserted Claims of the Patents-in-Suit by any third parties.

4. To the extent Plaintiffs prove direct infringement of the Asserted Claims by a third party (rather than by Eagle), whether Plaintiffs have failed to carry their burden of proving by a preponderance of the evidence that, if Eagle's ANDA

No. 211538 were to be approved by the FDA, the manufacture, use, sale, offer for sale, or importation of the drug that is the subject of that ANDA will actively induce infringement of any of the Asserted Claims of the Patents-in-Suit.

II. ISSUES OF UNENFORCEABILITY REMAINING TO BE LITIGATED

A. Inequitable Conduct

5. Whether Eagle has proven by clear and convincing evidence that the '526 patent is unenforceable due to inequitable conduct before the U.S. Patent & Trademark Office ("PTO") during prosecution of the '526 patent.

6. Whether Eagle has proven by clear and convincing evidence that the '209 patent is unenforceable due to inequitable conduct before the PTO during prosecution of the '209 patent.

7. Whether Eagle has proven by clear and convincing evidence that the '785 patent is unenforceable due to inequitable conduct before the PTO during prosecution of the '785 patent.

B. Infectious Unenforceability

8. Whether Eagle has proven by clear and convincing evidence that the '526 patent is unenforceable due to inequitable conduct before the PTO during prosecution of the '239 patent.

9. Whether Eagle has proven by clear and convincing evidence that the '209 patent is unenforceable due to inequitable conduct before the PTO during prosecution of the '239 patent.

10. Whether Eagle has proven by clear and convincing evidence that the '785 patent is unenforceable due to inequitable conduct before the PTO during prosecution of the '239 patent.

III. ISSUES OF INVALIDITY REMAINING TO BE LITIGATED

A. Anticipation

11. Whether Eagle has proven by clear and convincing evidence that claim 13 of the '526 patent is invalid as anticipated pursuant to 35 U.S.C. § 102.

12. Whether Eagle has proven by clear and convincing evidence that claims 1, 3, 4, 5, and 7 of the '209 patent are invalid as anticipated pursuant to 35 U.S.C. § 102.

13. Whether Eagle has proven by clear and convincing evidence that claims 1, 4, 5, and 8 of the '785 patent are invalid as anticipated pursuant to 35 U.S.C. § 102.

B. Obviousness

14. Whether Eagle has proven by clear and convincing evidence that claim 13 of the '526 patent is invalid as obvious to a person of ordinary skill in the art pursuant to 35 U.S.C. § 103.

15. Whether Eagle has proven by clear and convincing evidence that claims 1, 3, 4, 5, and 7 of the '209 patent are invalid as obvious to a person of ordinary skill in the art pursuant to 35 U.S.C. § 103.

16. Whether Eagle has proven by clear and convincing evidence that claims 1, 4, 5, and 8 of the '785 patent are invalid as obvious to a person of ordinary skill in the art pursuant to 35 U.S.C. § 103.

17. Whether Plaintiffs have failed to meet their burden of production to demonstrate that the prior art taught away from the claimed inventions recited in the Asserted Claims of the Patents-in-Suit.

18. Whether Plaintiffs have failed to meet their burden of production to demonstrate criticality to overcome the presumption that the Asserted Claims of the Patents-in-Suit are invalid as obvious.

C. Written Description

19. Whether Eagle has proven by clear and convincing evidence that claim 13 of the '526 patent is invalid for lack of written description pursuant to 35 U.S.C. § 112(a).

20. Whether Eagle has proven by clear and convincing evidence that claims 1, 3, 4, 5, and 7 of the '209 patent are invalid for lack of written description pursuant to 35 U.S.C. § 112(a).

21. Whether Eagle has proven by clear and convincing evidence that claims 1, 4, 5, and 8 of the '785 patent are invalid for lack of written description pursuant to 35 U.S.C. § 112(a).

D. Enablement

22. Whether Eagle has proven by clear and convincing evidence that claim 13 of the '526 patent is invalid for lack of enablement pursuant to 35 U.S.C. § 112(a).

23. Whether Eagle has proven by clear and convincing evidence that claims 1, 3, 4, 5, and 7 of the '209 patent are invalid for lack of enablement pursuant to 35 U.S.C. § 112(a).

24. Whether Eagle has proven by clear and convincing evidence that claims 1, 4, 5, and 8 of the '785 patent are invalid for lack of enablement pursuant to 35 U.S.C. § 112(a).

E. Indefiniteness

25. Whether Eagle has proven by clear and convincing evidence that claim 13 of the '526 patent is invalid for indefiniteness pursuant to 35 U.S.C. § 112(b).

26. Whether Eagle has proven by clear and convincing evidence that claims 1, 3, 4, 5, and 7 of the '209 patent are invalid for indefiniteness pursuant to 35 U.S.C. § 112(b).

27. Whether Eagle has proven by clear and convincing evidence that claims 1, 4, 5, and 8 of the '785 patent are invalid for indefiniteness pursuant to 35 U.S.C. § 112(b).

IV. ISSUES OF REMEDIES REMAINING TO BE LITIGATED

28. Whether Eagle is entitled to a judgment that the Asserted Claims of the Patents-in-Suit are invalid, unenforceable and/or not infringed.

29. Whether Eagle should be granted an award of costs and expenses in this action.

30. Whether this is an exceptional case under 35 U.S.C. § 285 such that Eagle is entitled to an award of attorneys' fees.

LEGAL AUTHORITY

I. HATCH-WAXMAN BACKGROUND

31. Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (“FDCA”), the FDA must approve all new drugs before they may be distributed in interstate commerce. 21 U.S.C. § 355(a). To secure approval for a new drug, an applicant may file a New Drug Application (“NDA”) that includes, for instance, a full description of the drug and data supporting its safety and efficacy, as well as any patents that claim the drug or a method of using the drug if a claim of patent infringement could reasonably be asserted. *Id.* at § 355(b)(1); 21 C.F.R. § 314.53(b). “The FDA publishes the names of approved drugs and their associated patent information in the *Approved Drug Products with Therapeutic Equivalence Evaluations* list, commonly referred to as the ‘Orange Book.’” *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1045 (Fed. Cir. 2010).

32. In an effort to increase competition and reduce drug prices, statute permits others seeking approval to market a generic version of a previously-approved drug (“NDA product”) to file an Abbreviated New Drug Application (“ANDA”). An ANDA “allows an applicant to rely on the safety and efficacy information for the listed drug if the applicant can show that the generic drug is ‘bioequivalent’ to the listed drug.” *Id.* (citing 21 U.S.C. § 355(b)(2), (j)).

33. If a proposed generic product (“ANDA product”) is rated “Q1/Q2” to a NDA product, the FDA has determined that the ANDA product is qualitatively and quantitatively the same as the NDA product, and will not require separate bioequivalence studies. 21 C.F.R. § 320.22(b)(1); *see also id.* § 314.94(a)(9)(iii).

34. The ANDA must specify the formulation and properties of the proposed ANDA product that will be marketed by the applicant, and provide specifications for parameters such as pH and impurities in accordance with good manufacturing practices. *Id.* § 314.94(a)(5)–(7), (9); *id.* § 314.50(d)(1)(i)–(ii); *see generally* 21 C.F.R. § 211 *et seq.* (Current Good Manufacturing Practices For Finished Pharmaceuticals).

35. Manufacturing specifications define properties the product must have throughout the manufacturing process. *Id.* § 211.110(a)–(c). “Release” specifications define properties the product must have on release from manufacturing. *Id.* § 211.165(a), (c)–(f). “Stability” specifications define properties the product must have after release and through its shelf life. *Id.* § 211.166(a).

36. An ANDA applicant must conduct stability studies to demonstrate that its proposed ANDA product will meet its specifications over its shelf life. *Id.* § 211.166. In such studies, the product may be stored under various conditions and appropriate measurements taken at regular intervals during the product’s shelf life, which are reported to the FDA. *Id.* § 211.166(b).

37. Once its ANDA is approved, an ANDA applicant may not market a product that does not comply with its ANDA specifications, without being subject to strict sanctions. *See, e.g.*, 21 U.S.C. §§ 331(d), 332(a), 333(a), 334(a)(1), 335b(a)(1), 335c(a)(1); *see also Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1249–50 (Fed. Cir. 2000).

38. Additionally, an ANDA applicant must certify under any one of four bases as to why the ANDA product will not infringe a patent: “(i) that such patent information has not been filed, (ii) that such patent has expired, (iii) . . . [the ANDA product will not be released before] the date on which such patent will expire, or (iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.” 21 U.S.C. § 355(j)(2)(A)(vii)(i)-(iv).

39. A certification of invalidity or noninfringement is called a “paragraph IV certification.” If an ANDA applicant certifies under paragraph IV, the applicant must also send a Notice Letter to the NDA holder and owner of the patents listed in the Orange Book to inform them of the ANDA and the allegations of invalidity and/or noninfringement. *Id.* § 355(b)(3); 21 C.F.R. § 314.95(a). Upon receiving the Notice Letter, the patent owner then has 45 days in which to bring a patent infringement suit, and FDA approval of the ANDA product is automatically subject to a 30-month stay. 21 U.S.C. § 355(c)(3)(C).

II. NONINFRINGEMENT

40. “The patentee bears the burden of proving infringement by a preponderance of the evidence.” *Vanda Pharm. Inc. v. W.-Ward Pharm. Int’l Ltd.*, 887 F.3d 1117, 1125 (Fed. Cir. 2018); accord, *Takeda Pharm. Co. v. Teva Pharm. USA, Inc.*, 668 F. Supp. 2d 614, 619 (D. Del. 2009) (“The patent owner has the burden of proving infringement and must meet its burden by a preponderance of the evidence.”).

41. Mere speculation cannot satisfy the patentee’s burden of proof. *See, e.g., Brigham & Women’s Hosp., Inc. v. Perrigo Co.*, 761 F. App’x 995, 1003–04 (Fed. Cir. 2019) (“At most, the study suggests that Pepcid Complete® might provide immediate and sustained relief; such speculative data, however, cannot sustain Brigham’s burden of proof.”).

42. An invalid claim cannot be infringed. *See Richdel, Inc. v. Sunspool Corp.*, 714 F.2d 1573, 1580 (Fed. Cir. 1983) (“The claim being invalid there is nothing to be infringed.”).

A. Infringement Under Hatch-Waxman

43. The filing of an ANDA application constitutes an “*artificial* act of infringement for purposes of establishing jurisdiction in the federal courts” under 35 U.S.C. § 271(e)(2), as the ANDA precedes any product that could constitute actual infringement under § 271(a). *Glaxo Grp. Ltd. v. Apotex, Inc.*, 376 F.3d 1339,

1551 (Fed. Cir. 2004); *see also Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990) (same); 35 U.S.C. § 271(e)(2) (“It shall be an act of infringement to submit (A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent.”).

44. The filing of an ANDA, however, does not by itself prove infringement. *See Ferring B.V. v. Watson Labs., Inc.-Fla.*, 764 F.3d 1401, 1408 (Fed. Cir. 2014) (*Ferring II*) (“The district court here thus erred to the extent that it read § 271(e) to mean that [defendant’s] act of filing an ANDA, by itself, establishe[s] infringement The filing only constituted a technical act of infringement for jurisdictional purposes.”).

45. Nor does the analysis under § 271(e)(2) “alter a patentee’s burden of proving infringement” by a preponderance of the evidence. *Glaxo, Inv. v. Novopharm, Ltd.*, 110 F.3d 1562, 1567 (Fed. Cir. 1997). That burden always remains with the patent owner. *See Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1327 (Fed. Cir. 2008) (noting that the “burden to prove infringement” never shifts from the plaintiff); *Amgen Inc. v. Apotex Inc.*, 712 F. App’x 985, 993 (Fed. Cir. 2017) (noting it is not the accused infringer’s “burden to prove non-infringement”).

46. In Hatch-Waxman cases, the question of infringement is a hypothetical one; “[t]he relevant inquiry is whether the patentee has proven by a preponderance

of the evidence that the alleged infringer will *likely* market an infringing product. What is likely to be sold, or, preferably, what will be sold, will ultimately determine whether infringement exists.” *Glaxo*, 110 F.3d at 1570 (emphasis added).

47. It is “the ANDA itself [that] dominates th[is] analysis.” *Ferring II*, 764 F.3d at 1408; *accord*, *Glaxo*, 110 F.3d at 1569 (“[T]his hypothetical inquiry is properly grounded in the ANDA application and the extensive materials typically submitted in its support.”).

48. Where “the ANDA is to sell a well-defined compound, then the ultimate question of infringement is usually straightforward.” *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1249 (Fed. Cir. 2000) (internal quotation marks and brackets omitted) (finding no infringement based entirely on defendant’s ANDA). That is, in instances where the ANDA specification “directly resolves the infringement question because it defines a proposed generic product in a manner that either meets the limitations of an asserted patent claim or is outside the scope of such a claim,” the inquiry ends. *Ferring II*, 764 F.3d at 1408; *accord*, *Ferring B.V. v. Watson Labs., Inc.-Fla.*, 764 F.3d 1382, 1389 (Fed. Cir. 2014) (*Ferring I*) (affirming district court’s determination of no infringement, finding that the “ANDA specification speaks directly to the question of infringement and would not permit [the ANDA filer] to market an infringing product”).

49. The hypothetical inquiry does not consider speculative allegations that an ANDA product may undergo changes, or the ANDA may be revised, at some point in the future. *See Bayer AG v. Biovail Corp.*, 279 F.3d 1340, 1349 (Fed. Cir. 2002) (endorsing the district court’s view that “[i]t is not enough for [the patentee] to suggest that the accused product may be infringing at some point in the future [due to changes in its properties]. The relevant test is whether [the applicant’s] drug, if put on the market, would infringe [the] patent.”); *see also AstraZeneca Pharm. LP v. Apotex Corp.*, 669 F.3d 1370, 1380–81 (Fed. Cir. 2012) (rejecting arguments that future amendments to an ANDA may result in infringement, and finding that “[s]ection 271(e)(2) does not encompass ‘speculative’ claims for infringement. . . . Regardless what may or may not occur in the future, the infringement analysis under § 271(e)(2) is limited to whether the accused infringer’s ANDA seeks approval for activities that would constitute infringement of the asserted patents.”) (citations omitted); *Par Pharm., Inc. v. Luitpold Pharm., Inc.*, 2017 WL 452003, at *6 (D.N.J. Feb. 2, 2017) (“Because Par’s claim is entirely premised on speculation that future, uncertain amendments to Luitpold’s ANDA will infringe Par’s patents, and there is no question that the drug specified in Luitpold’s ANDA does not infringe the Patents-in-Suit, judgment in favor of Luitpold is warranted.”).

50. Data submitted alongside the ANDA, even data tending to show infringement, is generally irrelevant when the specification “directly addresses the

question of infringement.” *Bayer*, 212 F.3d at 1249 (“[Plaintiff’s] focus on the biobatch [data], whose test data was submitted with [defendant’s] ANDA, is misplaced for two reasons. First, the [FDCA] specifically provides an ANDA applicant immunity from allegations of infringement for acts that are necessary in preparing an ANDA. . . . Second, the specification in [defendant’s] ANDA defines its product in a way that directly addresses the question of infringement.”); *see also In re Brominidine Patent Litig.*, 643 F.3d 1366, 1376–77 (Fed. Cir. 2011) (reversing judgment of infringement and rejecting reliance on expert testimony regarding testing data where the ANDA specified a pH outside the claimed range, finding “the highest pH at which Exela will manufacture and sell its proposed product is 6.7 or Exela will not, legally, market anything at all. . . . We cannot assume that Exela will not act in full compliance with its representations to the FDA.”).

51. In fact, when an ANDA specification does not infringe the patent on its face, one of the only times it may be appropriate to rely on extrinsic data is when such data shows infringement of the “actual commercial product with actual test results,” in spite of the non-infringing specification. *Biovail*, 279 F.3d at 1349. In such cases, the inquiry no longer concerns “what [the defendant] will likely market, but what [the defendant] has *actually* marketed.” *Id.* (emphasis added); *cf. Tyco Healthcare Grp. LP v. Mutual Pharm. Co.*, 762 F.3d 1338, 1344 (Fed. Cir. 2014) (noting, in the context of *Noerr-Pennington* immunity from antitrust liability, that

“it is not unreasonable for a patent owner to allege infringement under section 271(e)(2)(A) *if the patent owner has evidence that the as-marketed commercial ANDA product will infringe*, even though the hypothetical product specified in the ANDA could not infringe.” (emphasis added)).

52. In the context of the hypothetical inquiry (not actual infringement by an actual commercial product), only when “the ANDA specification does not resolve the infringement question in the first instance” do courts look to additional evidence, such as “biobatch data [or] actual samples of the proposed generic composition that the ANDA filer had submitted to the FDA.” *Ferring II*, 764 F.3d at 1409; *see also Bayer*, 212 F.3d at 1250 (if the ANDA specification does “not define the compound in a manner that directly addresse[s] the issue of infringement,” other data may then be considered); *Glaxo*, 110 F.3d at 1569–70 (looking to testing data when the drug product could exist in two forms only because the ANDA specification did address which form would be present in the likely ANDA product). Even then, reliance on “outliers” and “anomalies” in biobatch data cannot satisfy a patentee’s burden to “prove[] infringement by a preponderance of the evidence. . . .” *Ferring II*, 764 F.3d at 1409–10.

B. Direct Infringement

53. Under Section 271(a), “whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the

United States any patented invention during the term of the patent therefor, infringes the patent.” 35 U.S.C. § 271(a).

54. Determining direct infringement requires a two-step inquiry. Step one is to construe the disputed terms of the patent at issue; step two is to compare the accused products with the properly construed claims of the patent. *Alza Corp. v. Andrx Pharm., LLC*, 607 F. Supp. 2d 614, 623 (D. Del. 2009). Step one is a question of law; step two is a question of fact. *Id.*; *see also Wavetronix v. EIS Elec. Integrated Sys.*, 573 F.3d 1343, 1354 (Fed. Cir. 2009).

55. For method patents, direct infringement can occur only where “all steps of a claimed method are performed by or attributable to a single entity.” *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020, 1022 (Fed. Cir. 2015) (*en banc*) (citing *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1371, 1379–81 (Fed. Cir. 2007)).

56. “Literal infringement occurs when each element of at least one claim of the patent is found in the alleged infringer’s product.” *Alza*, 607 F. Supp. 2d at 623; *see also Microsoft Corp. v. GeoTag, Inc.*, 817 F.3d 1305, 1313 (Fed. Cir. 2016). “If any claim limitation is absent from the accused device, there is no literal infringement as a matter of law.” *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1247 (Fed. Cir. 2000); *Glaxo Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1566 (Fed. Cir. 1997) (“It is elementary patent law that all limitations are material,”

and plaintiffs are “required to establish the presence of each limitation of the asserted claims”).

C. Induced Infringement

57. “Whoever actively induces infringement of a patent shall be liable as an infringer.” 35 U.S.C. § 271(b).

58. “[L]iability for induce[d infringement] must be predicated on direct infringement.” *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 572 U.S. 915, 921 (2014). In other words, the patent owner must show that the alleged infringer, with knowledge of the asserted patents, “knowingly aided and abetted” another’s direct infringement. *Takeda Pharm. U.S.A., Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625, 630 (Fed. Cir. 2015). “[I]n the ANDA context, it is well-established that ‘mere knowledge of possible infringement by others does not amount to inducement; specific intent and action to induce infringement must be proven.’” *Id.* at 631; *see also DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1305 (Fed. Cir. 2006) (“[I]nducement requires that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another’s infringement.”) (internal quotations omitted); *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1363 (Fed. Cir. 2003) (“[P]roof of actual intent to cause the acts which constitute the infringement is a necessary prerequisite to finding active inducement.”).

59. “[The] sale of a lawful product by lawful means, with the knowledge that an unaffiliated, third party may infringe, cannot, in and of itself, constitute inducement of infringement.” *Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263, 1276 n. 6 (Fed. Cir. 2004) (internal quotation marks and citation omitted). Rather, “plaintiff has the burden of showing that the alleged infringer’s actions induced infringing acts and that he knew or should have known his actions would induce actual infringements.” *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 553 (Fed. Cir. 1990). “[T]he patentee must show that the accused inducer took an affirmative act to encourage infringement with the knowledge that the induced acts constitute patent infringement.” *Power Integrations, Inc. v. Fairchild Semiconductor*, 843 F.3d 1315, 1332 (Fed. Cir. 2016); *accord*, *DSU Med.*, 471 F.3d at 1306 (This requires “more than just intent to cause the acts that produce direct infringement”; rather, the patentee must prove that an accused infringer has “an *affirmative* intent to cause direct infringement”) (emphasis added). Stated differently, the patentee is “required to prove that: (1) a third party directly infringed the asserted claims of the . . . patents; (2) [the alleged infringer] induced those infringing acts; and (3) [the alleged infringer] knew the acts it induced constituted infringement.” *Id.*

60. In the ANDA context, “[t]he mere existence of direct infringement by physicians, while necessary to find liability for induced infringement, is not

sufficient for inducement.” *Takeda*, 785 F.3d at 631; *see also, e.g., United Therapeutics Corp. v. Sandoz, Inc.*, V.S. No. 12-CV-01617, 2014 WL 429153, at *21 (D.N.J. Aug. 29, 2014) (“It is not enough that ‘a user following the instructions may end up’ practicing the patented method.”). “This requirement of inducing acts is particularly important in the Hatch-Waxman Act context because the statute was designed to enable the sale of drugs for non-patented uses even though this would result in some off-label infringing uses.” *Takeda*, 785 F.3d at 631.

61. As such, “in the Hatch–Waxman Act context where . . . it is alleged that the drug label induces infringement by physicians,” “[t]he label must encourage, recommend, or promote infringement.” *Takeda*, 785 F.3d at 631. It is not enough that the “instructions describe the infringing mode.” *Id.* (internal quotation marks and brackets omitted); *accord Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 845 F.3d 1357, 1368 (Fed. Cir. 2017); *Grunenthal GMBH v. Alkem Labs. Ltd.*, 919 F.3d 1333, 1339-40 (Fed. Cir. 2019) (claims directed to a method of using tapentadol and tapentadol hydrochloride for the treatment of polyneuropathic pain were not directly or indirectly infringed by drug manufacturer, where the accused infringer’s proposed label did not indicate its drug product was to be used to treat polyneuropathic pain).

62. “[V]ague label language cannot be combined with speculation about how physicians may act to find inducement.” *Takeda*, 785 F.3d at 632. Indeed, “where a product has substantial non-infringing uses, intent to induce infringement

cannot be inferred even when the defendant has actual knowledge that some users of its product may be infringing the patent.” *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1329 (Fed. Cir. 2009) (citation omitted); *accord*, *Warner-Lambert*, 316 F.3d at 1365. At bottom, there can be no inducement simply because “a user following the instructions may end up using the device in an infringing way.” *Vita-Mix*, 581 F.3d at 1329 n.2.

63. A use that is permitted but not necessarily required by the label may not amount to inducement. *See Shire LLC v. Amneal Pharm., LLC*, C.A. No. 11-3781 (SRC), 2014 WL 2861430 at *4–5 (D.N.J. June 23, 2014), *aff’d*, 802 F.3d 1301 (Fed. Cir. 2015) (finding a label that instructed administration with or without food did not induce infringement of a patent that required administration with food); *see also In re Depomed Patent Litig.*, C.A. No. 13-4507 (CCC-MF), 2016 WL 7163647 at *58, *63–64 (D. N. J. Sept. 30, 2016), *aff’d sub. nom. Grunenthal GmbH v. Alkem Labs. Ltd.*, 919 F.3d 1333 (Fed. Cir. 2019) (finding a label that instructed administration for numerous reasons, including polyneuropathic pain, did not induce infringement of a patent that required for polyneuropathic pain, as the label did not *cause* its use for that purpose). Labeling instructions that demonstrate “indifference to the administration of the ANDA products [according to the claimed method]” do not “actively encourage or direct such administration.” *Otsuka Pharm. Co. v. Torrent Pharm. Ltd.*, 99 F. Supp. 3d 461, 493–94 (D.N.J. 2015).

D. Divided Infringement

64. Whereas direct infringement involves a single actor performing the entire claimed method, “[w]here more than one actor is involved in practicing the steps, a court must determine whether the acts of one are attributable to the other such that a single entity is responsible for the infringement.” *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020, 1022 (Fed. Cir. 2015) (*en banc*). To establish inducement of claim, a patentee must demonstrate “that joint direct infringement would occur, which requires that ‘the acts of one are attributable to the other such that a single entity is responsible for the infringement.’” *Pernix Ire. Pain DAC v. Alvogen Malta Operations Ltd.*, 323 F. Supp. 3d 566, 578 (D. Del. 2018) (quoting *Akamai Techs.*, 797 F.3d at 1022).

65. A “court will not ‘unilaterally restructure the claim or the standards for joint infringement to remedy [] ill-conceived claims’ requiring multiple parties to perform different acts within one claim.” *CBA Env'tl. Servs., Inc. v. Toll Brothers Inc.*, 403 F. Supp. 3d 403, 418 (D.N.J. 2019) (alteration in original) (citation omitted).

66. “[A]n entity responsible for others’ performance of method steps in two sets of circumstances: (1) where that entity directs or controls others’ performance, and (2) where the actors form a joint enterprise.” *Akamai Techs.*, 797 F.3d at 1022.

67. To pursue a joint enterprise theory, the patent holder must allege facts sufficient to substantiate four elements: “(1) an agreement, express or implied, among the members of the group; (2) a common purpose to be carried out by the group; (3) a community of pecuniary interest in that purpose, among the members; and (4) an equal right to a voice in the direction of the enterprise, which gives an equal right of control.” *Sonrai Sys., LLC v. AMCS Grp. Inc.*, C.A. No. 16 C 9404, 2017 WL 4281122, at *4 (N.D. Ill. Sept. 27, 2017) (quoting *Akamai Techs.*, 797 F.3d at 1023).

68. “Under either the agency or joint enterprise theories of direct infringement, [one entity] would have to exercise a degree of control over . . . the other entity allegedly involved in the infringement: for an agency theory, the authority of a principal, or for a joint enterprise, an equal voice in the direction of the enterprise.” *Sonrai Sys.*, 2017 WL 4281122, at *6.

69. As such, to determine whether the “entity directs or controls” another’s performance, courts will apply the general principles of vicarious liability, including whether the entity “acts through an agent (applying traditional agency principles)” or through a contract “to perform one or more steps of the claimed method.” *Akamai Techs.*, 797 F.3d at 1022–23. “The ‘control or direction’ standard is ‘satisfied in situations where the law would traditionally hold the accused direct infringer vicariously liable for the acts committed by another party that are required to

complete performance of a claimed method.” *CBA Envtl.*, 403 F. Supp. 3d at 418 (citation omitted).

70. “Direction and control can be shown where an actor ‘(1) “conditions participation in an activity or receipt of a benefit” upon others’ performance of one or more steps of a patented method, and (2) “establishes the manner or timing of that performance.”’” *Pernix Ire.*, 323 F. Supp. 3d at 580 (quoting *Akamai Techs.*, 797 F.3d at 1023). “Accordingly, the ‘direction or control’ test requires the controlling party to be, in effect, the ‘mastermind’ of the entire process.” *CBA Envtl.*, 403 F. Supp. 3d at 418 (citation omitted).

71. A “contractual relationship between [two entities] is not sufficient, by itself, to state a claim for joint-direct infringement: the test for direction and control is analogous to the test for vicarious liability, and a contracting party is not vicariously liable for the actions of an independent contractor unless that party controls the details of the independent contractor’s work to such an extent that the contractor cannot perform the work as he chooses.” *CBA Envtl.*, 403 F. Supp. 3d at 418. “Moreover, the existence of a contractual relationship may, in some instances, be suggestive of one party’s control and direction, but the necessary level of control ‘requires more than a general right to order work stopped or resumed, to inspect its process or to receive reports, to make suggestions or recommendations which need

not necessarily be followed, or to prescribe alterations and deviations” *Id.* at 419 (alterations in original) (citation omitted).

72. “[M]ere ‘arms-length cooperation’ will not give rise to a claim for joint-direct infringement.” *CBA Env'tl.*, 403 F. Supp. 3d at 418.

73. “[P]hysicians, and hospital, and hospital staff [do not necessarily] constitute one entity when determining if all the steps are” performed by a single entity. *CR Bard Inc. v. AngioDynamics Inc.*, 382 F. Supp. 3d 332, 336–37 (D. Del. 2019).

III. UNENFORCEABILITY

A. Inequitable Conduct

74. Inequitable conduct is an equitable defense to patent infringement. *Therasense Inc. v. Becton Dickinson & Co.*, 649 F.3d 1276, 1285 (Fed. Cir. 2011). A finding of “fraud,” “inequitable conduct,” or violation of duty of disclosure with respect to any claim in an application or patent, renders all the claims thereof unpatentable or invalid. *See id.* at 1288. “[I]nequitable conduct infects the invention itself, and all claims which form a part of that invention.” *Robocast, Inc. v. Microsoft Corp.*, 21 F. Supp. 3d 320, 338 (D. Del. 2014). As such, “the taint of a finding of inequitable conduct can spread from a single patent to render unenforceable other related patents and applications in the same technology family.” *Therasense*, 649 F.3d at 1288 (citing *Consol. Aluminum Corp. v. Foseco Int’l Ltd.*, 910 F.2d 804,

808–12 (Fed. Cir. 1990)); *see also eSpeed Inc. v. Brokertec USA LLC*, 417 F. Supp. 2d 580, 595 (D. Del. 2006) (inequitable conduct during the prosecution of a patent application “can therefore render unenforceable . . . claims that issue from related applications as well”), *aff’d*, 480 F.3d 1129 (Fed. Cir. 2007).

75. Evidence “that the patent applicant (1) misrepresented or omitted information material to patentability, and (2) did so with specific intent to mislead or deceive” the PTO requires a finding that the patent is unenforceable due to inequitable conduct. *Intellect Wireless, Inc. v. HTC Corp.*, 732 F.3d 1339, 1341–42 (Fed. Cir. 2013); *accord, Ohio Willow Wood Co. v. Alps South, LLC*, 735 F.3d 1333, 1344 (Fed. Cir. 2013). The determination of inequitable conduct is a flexible doctrine based on the Court’s equitable powers, which is “not bound by formula or restrained by any limitation that tends to trammel the free and just exercise of discretion.” *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 245–46 (1933).

1. *Patentee’s Duty of Candor*

76. The duty owed to the PTO includes those whose “involvement relates to the content of the application or decisions related thereto, and . . . is not wholly administrative or secretarial in nature.” *Avid Identification Sys., Inc. v. Crystal Imp. Corp.*, 603 F.3d 967, 974 (Fed. Cir. 2010). The person who misrepresents or omits material information can be an inventor, prosecuting attorney, or a person otherwise

“substantively involved in the preparation or prosecution of the [patent] application.” *Id.* at 973. The proper resolution of inequitable conduct requires evaluating the actions of all involved. *See, e.g., TransWeb, LLC v. 3M Innovative Props. Co.*, 16 F. Supp. 3d 385, 406–07 (D.N.J. 2014) (“[T]he actions of other 3M employees—Rousseau, Legare, Nagel, Lyons, and others—provide strong corroborating evidence of the inequitable conduct of Jones and Hanson.”), *aff’d*, 812 F.3d 1295 (Fed. Cir. 2016). The Court’s determination of inequitable conduct should not be “bound by formula” and need not be adjudicated with respect to each individual in isolation. *Keystone Driller*, 290 U.S. at 245–46.

77. All individuals covered by 37 C.F.R. § 1.56 have a duty to disclose to the PTO all material information they are *aware* of, regardless of the source of or how they become aware of the information. *See Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1383 (Fed. Cir. 2001) (“Once an attorney, or an applicant has notice that information exists that appears material and questionable, that person cannot ignore that notice in an effort to avoid his or her duty to disclose.”).

2. Materiality

78. Materiality is established if the PTO would not have issued the claim if it had been aware of the omitted or misrepresented information. *Aventis Pharma S.A. v. Hospira, Inc.*, 675 F.3d 1324, 1334 (Fed. Cir. 2012) (quoting *Therasense*,

649 F.3d at 1291); *Belcher Pharm., LLC v. Hospira, Inc.*, 450 F. Supp. 3d 12, 549–51 (D. Del. 2020) (finding prior art products having a pH within the claimed range material to prosecution where patentee argued that the claimed pH was critical over a broader pH range disclosed in the prior art).

79. The materiality required to establish inequitable conduct is “but-for” materiality. *Aventis Pharma*, 675 F.3d at 1334 (citing *Therasense*, 649 F.3d at 1291). However, but-for materiality need not be shown for “affirmative acts of egregious misconduct.” See *Therasense*, 649 F.3d at 1292–93 (contrasting against “mere nondisclosure of prior art” and deliberate omission by “fail[ing] to mention prior art references in an affidavit”). Indeed, but-for materiality is presumed where “the patentee has engaged in affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit.” *Therasense*, 649 F.3d at 1292–93 (citing *Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556, 1571 (Fed. Cir. 1983) (“there is no room to argue that submission of false affidavits is not material”)); see also *Ohio Willow Wood*, 735 F.3d at 1345. “After all, a patentee is unlikely to go to great lengths to deceive the PTO with a falsehood unless it believes that the falsehood will affect issuance of the patent.” *Therasense*, 649 F.3d at 1292.

80. Because the PTO applies a preponderance of the evidence standard and gives claims their broadest reasonable interpretation, a defendant can show materiality under a preponderance of the evidence standard even if the issued claims

are not invalidated by clear and convincing evidence at trial. *Aventis Pharma*, 675 F.3d at 1334 (citing *Therasense*, 649 F.3d at 1291–92).

81. The selective disclosure of material information to other recipients, but not to the PTO, supports the inference that an inventor understood the importance of the material and withheld it from the PTO with deceptive intent. See *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs. Ltd.*, 394 F.3d 1348, 1354 (Fed. Cir. 2005); *A.B. Dick Co. v. Burroughs Corp.*, 798 F.2d 1392, 1399 (Fed. Cir. 1986).

82. A finding of patent validity does not bind the Court’s decision on materiality. As the Federal Circuit in *American Calcar v. American Honda Motor Co.* stated:

This court held in *Therasense* that the standard for ‘the materiality required to establish inequitable conduct is but-for materiality.’ In particular, undisclosed prior art is ‘but-for material if the PTO would not have allowed a claim had it been aware of’ it. This means that to assess materiality, the court must look to the standard used by the PTO to allow claims during examination. To wit: ‘The court should apply the preponderance of the evidence standard and give claims their broadest reasonable construction.’ District courts and the PTO employ different evidentiary standards and rules for claim construction. Therefore, ‘even if a district court does not invalidate a claim based on a deliberately withheld reference, the reference may be material if it would have blocked patent issuance under the PTO’s different evidentiary standards.’ The jury’s verdict finding the patents at issue non-obvious thus does not weigh on the determination of materiality for inequitable conduct, and indeed, *Calcar* does not make any arguments on appeal that rely on the jury’s determination.

768 F.3d 1185, 1189 (Fed. Cir. 2014) (internal citations omitted).

83. Even though the attorney, agent, or applicant does not consider a reference or information necessarily material, “where the materiality of the information is uncertain, disclosure is required.” *Brasseler*, 267 F.3d at 1386; *see also, e.g., LaBounty Mfg., Inc. v. U.S. Int’l Trade Comm’n*, 958 F.2d 1066, 1076 (Fed. Cir. 1992).

3. Intent to Deceive

84. “Direct evidence of intent or proof of deliberate scheming is rarely available in instances of inequitable conduct, but intent may be inferred from the surrounding circumstances.” *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed. Cir. 1997); *see also Paragon Podiatry Lab., Inc. v. KLM Labs., Inc.*, 984 F.2d 1182, 1189–91 (Fed. Cir. 1993) (“‘[S]moking gun’ evidence is not required in order to establish an intent to deceive. Rather, this element of inequitable conduct . . . must generally be inferred from the facts and circumstances surrounding the applicant’s overall conduct.”). “[A] district court may infer intent from indirect and circumstantial evidence.” *Therasense*, 649 F.3d at 1290. “[I]n the absence of a credible explanation, intent to deceive is generally inferred from the facts and circumstances surrounding a knowing failure to disclose material information.” *Bruno*, 394 F.3d at 1354. Where the single most reasonable inference from the circumstantial evidence is intent to deceive, specific intent is satisfied. *See Therasense*, 649 F.3d at 1290; *see also Aventis Pharma*, 675 F.3d at

1335 (“specific intent to deceive must be the single most reasonable inference able to be drawn from the evidence” (citations and quotations omitted)).

85. The Court may take into account circumstances where a witness’s “memory of facts was suspiciously selective, and he refused to acknowledge certain incontrovertible events.” *Avid*, 603 F.3d at 975. Contradictions and shifting explanations are strong evidence of deceptive intent. *Advanced Magnetic Closures, Inc. v. Rome Fastener Corp.*, 607 F.3d 817, 830 (Fed. Cir. 2010) (finding “evasive, argumentative, and at times contradictory testimony” evidence of deceptive intent).

86. In the absence of a good faith explanation for failing to disclose material information, deceptive intent is the single most reasonable inference. *Critikon*, 120 F.3d at 1256–57 (“[A] patentee facing a high level of materiality and clear proof that it knew or should have known of that materiality, can expect to find it difficult to establish ‘subjective good faith’ sufficient to prevent the drawing of an inference of intent to mislead.”); *Merck & Co. v. Danbury Pharmacal, Inc.*, 873 F.2d 1418, 1422 (Fed. Cir. 1989) (stating intent is often proven by “a showing of acts the natural consequences of which are presumably intended by the actor” (citation omitted)).

87. “Partial disclosure of material information about the prior art to the PTO cannot absolve a patentee of intent if the disclosure is intentionally selective.” *See Am. Calcar*, 768 F.3d at 1190–91 (finding intent where Calcar’s founder, Mr.

Obradovich, “was not candid about the inventors’ possession of photographs” of the prior art, and “knew the information was material because he himself acknowledged the importance of the information he possessed”).

88. Where a prosecuting attorney’s “statements were not mere advocacy for a preferred interpretation . . . [but] factual in nature and contrary to the true information he had in his possession,” those statements cross “the line from legitimate advocacy to genuine misrepresentation of material facts,” supporting a finding of inequitable conduct. *See Apotex Inc. v. UCB, Inc.*, 763 F.3d 1354, 1362 (Fed. Cir. 2014); *see also Regeneron Pharm., Inc. v. Merus B.V.*, 144 F. Supp. 3d 530, 583 (S.D.N.Y. 2015) (finding that “incomplete and/or inaccurate” statements about scientific data support inequitable conduct), *aff’d*, 864 F.3d 1343 (Fed. Cir. 2017).

89. “[I]t can be expected that an innocent party will be motivated to try to present convincing reasons for its actions or inaction.” *Bruno*, 394 F.3d at 1354. “[A]n inference of deceptive intent may fairly be drawn in the absence of” any “credible explanation” for nondisclosure or material misrepresentation. *Id.* And “[i]n the absence of a credible explanation, intent to deceive is generally inferred from the facts and circumstances surrounding a knowing failure to disclose material information.” *Id.*

90. If the accused infringer meets its burden to prove inequitable conduct, “then the district court must weigh the equities to determine whether the applicant’s conduct before the PTO warrants rendering the entire patent unenforceable.” *Therasense*, 649 F.3d at 1287. Inequitable conduct related to even a “single claim renders the entire patent unenforceable.” *Id.* at 1288; *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 874 (Fed. Cir. 1988).

B. Infectious Unenforceability

91. “The duty of candor extends throughout the patent’s entire prosecution history. . . . Therefore, a breach of the duty of candor early in the prosecution may render unenforceable all claims which eventually issue from the same or a related application.” *Fox Indus., Inc. v. Structural Pres. Sys., Inc.*, 922 F.2d 801, 803–04 (Fed. Cir. 1990); *see also Agfa Corp. v. Creo Prods. Inc.*, 451 F.3d 1366, 1379 (Fed. Cir. 2006) (holding continuation patent unenforceable based on inequitable conduct found in the prosecution of the parent application); *Nilssen v. Osram Sylvania, Inc.*, 504 F.3d 1223, 1230 (Fed. Cir. 2007).

92. “The doctrine[] of infectious unenforceability [is] closely related to the doctrine of inequitable conduct.” *Hoffman-La Roche, Inc. v. Promega Corp.*, 319 F. Supp. 2d 1011, 1017 (N.D. Cal. 2004). Infectious unenforceability may arise when “an unconscionable act that occurs during the prosecution of one patent has an immediate and necessary relation to the equity sought in the prosecution of another

patent.” *Id.* As such, “the taint of a finding of inequitable conduct can spread from a single patent to render unenforceable other related patents and applications in the same technology family.” *Therasense*, 649 F.3d at 1288. Indeed, “a finding of inequitable conduct may endanger a substantial portion of a company’s patent portfolio.” *Id.*

93. Infectious unenforceability arises so long as the inequitable conduct as to one patent bears “an immediate and necessary relation” to enforcement of the related patent. *eSpeed*, 417 F. Supp. 2d at 595; *see also* Report and Recommendation, *Guardant Health, Inc. v. Found. Med., Inc.*, 1-17-cv-01616, D.I. 343 at 8–9 (D. Del. Jan. 7, 2020) (quoting *Consol. Aluminum*, 910 F. 2d at 812), *Report and Recommendation adopted*, C.A. No. 17-1616-LPS-CJB, 2020 WL 1329513, at *5 (D. Del. Mar. 23, 2020). That is, “the inequitable conduct that occurred earlier in the chain [of issued patents] ‘must be related to the targeted claims of the ultimately-issued patent or patents sought to be enforced.’” *eSpeed*, 417 F. Supp. 2d at 595 (quoting *Semiconductor Energy Lab., Inc. v. Samsung Elecs. Co.*, 24 F. Supp. 2d 537, 543 (E.D. Va. 1998)); *Truth Hardware Corp. v. Ashland Prods., Inc.*, No. 02-1541 GMS, 2003 WL 22005839, at * 1 (D. Del. Aug. 19, 2003). This may include, for instance, a continuation application that is not “sufficiently distinct from its parent.” *Agfa*, 451 F.3d at 1379.

IV. INVALIDITY

94. The burden rests on a party challenging the patent to show invalidity by clear and convincing evidence. *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 100 (2011); *Apotex USA, Inc. v. Merck & Co.*, 254 F.3d 1031, 1036 (Fed. Cir. 2001). Clear and convincing evidence is evidence that “could place in the ultimate factfinder an abiding conviction that the truth of [the] factual contentions are ‘highly probable.’” *Colorado v. New Mexico*, 467 U.S. 310, 316 (1984); *see also Procter & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 994 (Fed. Cir. 2009).

95. Once the challenging party “has presented a prima facie case of invalidity, the patentee has the burden of going forward with rebuttal evidence.” *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1360 (Fed. Cir. 2007). If the patentee fails to do so, the patent cannot be found valid. *See, e.g., Ralston Purina Co. v. Far-Mar-Co.*, 772 F.2d 1570, 1573 (Fed. Cir. 1985) (“If this burden [of making a prima facie case of invalidity] is met, the party relying on validity is then obligated to come forward with evidence to the contrary.”).

96. “The courts are the final arbiter of patent validity and, although courts may take cognizance of, and benefit from, the proceedings before the patent examiner, the question is ultimately for the courts to decide, without deference to the rulings of the patent examiner.” *Quad Envtl. Techs. Corp. v. Union Sanitary Dist.*, 946 F.2d 870, 876 (Fed. Cir. 1991). Any relevant evidence, whether or not

previously considered by the PTO, can be considered by the court in determining validity. *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1571–72 (Fed. Cir. 1988).

97. A “commonsense principle that the Federal Circuit has recognized throughout its existence” is “that new evidence supporting an invalidity defense may carry more weight in an infringement action than evidence previously considered by the PTO.” *Microsoft Corp.*, 564 U.S. at 110 (quotations omitted). While the Supreme Court has “not reach[ed] the question whether the failure to disclose [an invalidating prior art reference] during the prosecution of [the patent-in-suit] voids the presumption of validity given to issued patents,” it “nevertheless . . . note[d] that the rationale underlying the presumption—that the PTO, in its expertise, has approved the claim—seems much diminished” in that context. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 426 (2007).

A. Prior Art

98. Section 102(a) of the America Invents Act (AIA) provides:

A person shall be entitled to a patent unless—

- (1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or
- (2) the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

35 U.S.C. § 102(a).

99. Section 102 does not state the only sources of prior art. *In re Fout*, 675 F.2d 297, 300–01 (C.C.P.A. 1982). An inventor’s admission that he “had actual knowledge of [a] prior . . . invention . . . constitutes an admission that it is prior art to” him. *Id.* at 301; *Baxter Diagnostics Inc. v. AVL Sci. Corp.*, 924 F. Supp. 994, 1007 (C.D. Cal. 1996).

100. “Once [a pharmaceutical] formulation was disclosed in full to [a third party], without any restriction on its use, it had been released into the ‘public domain’ for purposes of § 102[b].” *Pronova Biopharm Norge AS v. Teva Pharm. USA, Inc.*, 549 F. App’x 934, 942–43 (Fed. Cir. 2013).

101. “Section 102[a] may create a bar to patentability either alone, if the device placed on sale is an anticipation of the later claimed invention or, in conjunction with 35 U.S.C. § 103 (1988), if the claimed invention would have been obvious from the on-sale device in conjunction with the prior art.” *LaBounty Mfg., Inc. v. U.S. Int’l Trade Comm’n*, 958 F.2d 1066, 1071 (Fed. Cir. 1992).

102. “If a product that is offered for sale inherently possesses each of the limitations of the claims, then the invention is on sale, whether or not the parties to the transaction recognize that the product possesses the claimed characteristics.” *Abbott Labs. v. Geneva Pharm., Inc.*, 182 F.3d 1315, 1319 (Fed. Cir. 1999); *see also*, *e.g.*, *Taro Pharm. U.S.A., Inc. v. Perrigo Isr. Pharm. Ltd.*, C.A. 14-cv-989-RGA,

2015 WL 7737310, at *2 (D. Del. Dec. 1, 2015) (“In response, Hill argues that Derma-Smoothe cannot possibly constitute invalidating prior art, as its formulation was—and still is—secret, and therefore could not be ‘known to someone of ordinary skill in the art.’ The secret nature of Derma-Smoothe does not foreclose its relevance to the § 103 inquiry.”). “[T]he question is not whether the sale, even a third party sale, ‘discloses’ the invention at the time of the sale, but whether the sale relates to a device that *embodies* the invention.” *J.A. LaPorte, Inc. v. Norfolk Dredging Co.*, 787 F.2d 1577, 1583 (Fed. Cir. 1986).

103. “A bar under § 102[] arises where, before the critical date, the invention is in public use and ready for patenting.” *E.g., Invitrogen Corp. v. Biocrest Mfg., L.P.*, 424 F.3d 1374, 1379 (Fed. Cir. 2005). “Public use . . . includes any use of the claimed invention by a person other than the inventor who is under no limitation, restriction or obligation of secrecy to the inventor.” *Art+Com Innovationpool GmbH v. Google LLC*, 712 F. App’x 976, 980 (Fed. Cir. 2017).

104. “The fact that the device was not hidden from view may make the use not secret but non-secret use is not *ipso facto* ‘public use’ activity. Nor, it must be added, is all secret use *ipso facto* not ‘public use’ within the meaning of the statute, if the inventor is making commercial use of the invention under circumstances [that] preserve its secrecy.” *New Railhead Mfg., LLC v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1299 (Fed. Cir. 2002) (alterations in original) (citations omitted)

105. “Beyond this ‘in public use or on sale’ finding, there is no requirement for an enablement-type inquiry.” *In re Epstein*, 32 F.3d 1559, 1567–68 (Fed. Cir. 1994).

106. Placing a composition on sale, including with instructions to practice a method, places the method of using those compositions on sale. *See, e.g., Enzo Biochem, Inc. v. Gen-Probe Inc.*, 424 F.3d 1276, 1285 (Fed. Cir. 2005) (“The shipment to Ortho consisted not only of the GC155 probe, but also accompanying instructions as to how to use the probe in the hybridization assay. Moreover, given that the composition claims read on probes that hybridize with *N. gonorrhoeae*, carrying out such a hybridization assay is inseparable from the compositions themselves. Effectively, the offer to sell the compositions invalidates claims 5 and 6 based on those same probes.”).

107. Apart from prior art references, “[a]dmissions in the specification regarding the prior art are binding on the patentee for purposes of a later inquiry into obviousness.” *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1362 (Fed. Cir. 2007); *Sjolund v. Musland*, 847 F.2d 1573, 1577–79 (Fed. Cir. 1988) (admission in the patent specification “must [be] accepted . . . as prior art, as a matter of law”); *In re Nomiya*, 509 F.2d 566, 570–71 (C.C.P.A. 1975) (representations in the specification are “accepted at face value as admissions” of what is “considered ‘prior art’ for any purpose, including use as evidence of obviousness under § 103”).

108. Section 102(b)(1) sets forth limited exceptions to what constitutes prior art under § 102(a)(1). It provides:

A disclosure made 1 year or less before the effective filing date of a claimed invention shall not be prior art to the claimed invention under subsection (a)(1) if—

(A) the disclosure was made by the inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or

(B) the subject matter disclosed had, before such disclosure, been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor.

35 U.S.C. § 102(b)(1).

109. Section 102(b)(1) was intended to codify the one-year grace period for public disclosures by or obtained through an inventor. *See* Robert A. Armitage, *Understanding the America Invents Act and Its Implications for Patenting*, 40 AIPLA Q. J. 1, 72 (2012) (“the two subparagraph (A) exceptions [(i.e. § 102(b)(1) and (2)] contain no substantive differences from one another in the sense that a disclosure reflecting the work of the inventor (or a joint inventor), rather than an independent creator of the subject matter disclosed, made during the one-year ‘grace period’ prior to the effective filing date of the inventor's claimed invention, is excepted from prior art . . . [and thus] provide no more and no less than a new codification of the pre-AIA grace period.”); N. Scott Lierce, *Invetorship, Double Patenting, and the America Invents Act*, 30 Berkeley Tech. L.J. 1613, 1616 (2015) (“‘Grace periods’ play an important role under the AIA because disclosure of

components that are the work of the *same inventive entity* as the claimed combination can be excepted from prior art under the AIA, as they were under the provisions of the Patent Act of 1952.”).

110. According to the PTO’s interpretation of § 102(b)(1)(A), in cases where the alleged prior art names individuals in addition to the inventors of the patent application, “it is incumbent upon the applicant to provide a satisfactory showing that the additional named authors did not contribute to the claimed subject matter.” *Examination Guidelines for Implementing the First Inventor to File Provisions of the Leahy-Smith America Invents Act*, 78 Fed. Reg. 11059, 11064–65 (Feb. 14, 2013).

B. Anticipation

111. Under 35 U.S.C. § 102(a)(1), a patent claim is invalid if “the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.”

112. “A patent is invalid for anticipation if a single prior art reference discloses each and every limitation of the claimed invention.” *Schering Corp. v. Geneva Pharm., Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003).

113. Anticipation is not limited to what the prior art expressly discloses—anticipation also extends to what the prior art inherently discloses. *Impax Labs., Inc.*

v. Aventis Pharm. Inc., 468 F.3d 1366, 1381 (Fed. Cir. 2006) (“A patent claim is invalid as anticipated if every limitation in a claim is found in a single prior art reference, either explicitly or inherently.”). For “a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference.” *Schering Corp.*, 339 F.3d at 1337; *see also, e.g., Purdue Pharma L.P. v. Epic Pharma, LLC*, 811 F.3d 1345, 1351 (Fed. Cir. 2016) (“A single prior art reference may anticipate without disclosing a feature of the claimed invention if such feature is necessarily present, or inherent, in that reference.”).

114. “[I]nherent anticipation does not require a person of ordinary skill in the art to recognize the inherent disclosure in the prior art at the time the prior art is created.” *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1343 (Fed. Cir. 2005); *see also Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999) (“[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art’s functioning, does not render the old composition patentably new to the discoverer.”).

115. “[A] prior art product that sometimes, but not always, embodies a claimed method nonetheless teaches that aspect of the invention.” *King Pharms., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1276 (Fed. Cir. 2010) (alteration in original)

(quoting *Hewlett-Packard Co. v. Mustek Sys., Inc.*, 340 F.3d 1314, 1326 (Fed. Cir. 2003)).

116. “A reference includes an inherent characteristic if that characteristic is the ‘natural result’ flowing from the reference’s explicitly explicated limitations.” *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 970 (Fed. Cir. 2001).

117. “Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates.” *E.g., Cubist Pharm., Inc. v. Hospira, Inc.*, 75 F. Supp. 3d 641, 650 (D. Del. 2014).

118. “To anticipate, the prior art need only meet the inherently disclosed limitation to the extent the patented method does.” *King Pharms.*, 616 F.3d at 1276.

119. “Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art.” *Atlas Powder*, 190 F.3d at 1347 (citing *Titanium Metals v. Banner*, 778 F.2d 775, 782 (Fed. Cir. 1985)).

120. “Extrinsic evidence ‘may be used to interpret the allegedly anticipating reference and [to] shed light on what it would have meant to’ a POSA. *Monsanto Tech. LLC v. E.I. DuPont de Nemours & Co.*, 878 F.3d 1336, 1345 (Fed. Cir. 2018) (alterations in original) (citation omitted). Such “extrinsic evidence need not antedate the critical date of the patent at issue.” *Id.* (citation omitted).

121. A reference that discloses a range that touches or overlaps a claimed value can anticipate the claim. *ClearValue Inc. v. Pearl River Polymers Inc.*, 668 F.3d 1340, 1344–45 (Fed. Cir. 2012) (the claimed range of 50 ppm or less was anticipated by the prior art disclosure of 150 ppm or less because no demonstration or claim that 50 ppm or less was “‘critical,’ or that the claimed method works different at different points within the prior art range”). *Perricone v. Medicis Pharmaceutical Corp.* is also instructive. In *Perricone*, the Federal Circuit affirmed the district court’s summary judgment of invalidity after finding, *inter alia*, that the prior art “nonetheless discloses and anticipates [the inventor’s] particular claimed ‘effective amount’ ranges” even though the prior art’s disclosed range “does not exactly correspond to [the inventor’s] claimed range.” 432 F.3d 1368, 1377 (Fed. Cir. 2005). As the Court noted, the prior art’s range “entirely encompasses, and does not significantly deviate from, [the inventor’s] claimed ranges,” therefore warranting a finding of anticipation. *Id.*

122. Anticipation is a question of fact. *In re Gleave*, 560 F.3d 1331, 1334–35 (Fed. Cir. 2009).

C. Obviousness

123. Section 103 provides:

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been

obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.

35 U.S.C. § 103. The prior art that is used for determining if the difference between the claimed subject matter and the prior art is obvious is any of the same prior art that is described in Section 102.

124. Obviousness is a question of law based on four underlying factual determinations: (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the pertinent art; and (4) secondary considerations, if any, of nonobviousness. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406–07 (2007) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966)).

125. “Nothing in [35 U.S.C. § 103] or [Federal Circuit] case law requires [a defendant] to prove obviousness by starting with a prior art commercial embodiment and then providing motivation to alter that commercial embodiment.” *Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 737 (Fed. Cir. 2013). “This is particularly true where, as here, the prior art teaches a range that encompasses both the prior art commercial embodiment and the claimed invention.” *Id.*

126. “[T]he scope of the relevant prior art . . . includ[es] that reasonably pertinent to the particular problem with which the inventor was involved.” *In re GPAC Inc.*, 57 F.3d 1573, 1577 (Fed. Cir. 1995) (quotation omitted). “A reference

is reasonably pertinent if, even though it may be in a different field of endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem." *Id.* at 1578 (quotation omitted). "If a reference disclosure relates to the same problem as that addressed by the claimed invention, that fact supports use of that reference in an obviousness [finding]." *Id.* (quotation omitted).

127. "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). "[A] finding that the prior art as a whole suggests the desirability of a particular combination need not be supported by a finding that the prior art suggests that the combination claimed by the patent applicant is the preferred, or most desirable." *In re Fulton*, 391 F.3d 1195, 1200 (Fed. Cir. 2004). "[J]ust because 'better alternatives' may exist in the prior art 'does not mean that an inferior combination is inapt for obviousness purposes.'" *Dome Patent L.P. v. Lee*, 799 F.3d 1372, 1381 (Fed. Cir. 2015) (quoting *In re Mouttet*, 686 F.3d 1322, 1334 (Fed. Cir. 2012)).

128. Where the prior art alone establishes enablement of the claimed subject matter, "[a] patent cannot both be non-obvious and enabled." *In re '318 Patent Infringement Litig.*, 578 F. Supp. 2d 711, 735 (D. Del. 2008). Conversely, "a description that does not render a claimed invention obvious does not sufficiently

describe that invention for purposes of § 112, ¶ 1.” *Regents of Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1567 (Fed. Cir. 1997) (emphasis omitted).

129. “[I]f a device was in public use or on sale before the critical date, then that device becomes a reference under section 103 against the claimed invention.” *E.g., Taro Pharms. U.S.A., Inc. v. Perrigo Isr. Pharms. Ltd.*, No. 14-cv-989-RGA, 2015 WL 7737310, at *2 (D. Del. Dec. 1, 2015). “The court’s task upon such a challenge is to determine whether the claimed invention would have been obvious from the on-sale device in conjunction with the prior art.” *TorPharm, Inc. v. Ranbaxy Pharm., Inc.*, 336 F.3d 1322, 1327 (Fed. Cir. 2003).

130. “[T]he public use bar applies to obvious variants of the demonstrated public use.” *Clock Spring, L.P. v. Wrapmaster, Inc.*, 560 F.3d 1317, 1326 (Fed. Cir. 2009) (citing *Netscape Commc’ns Corp. v. Konrad*, 295 F.3d 1315, 1321 (Fed. Cir. 2002)).

131. “Where a claimed range overlaps with a range disclosed in the prior art, there is a presumption of obviousness.” *Ormco Corp. v. Align Tech., Inc.*, 463 F. 3d 1299, 1311 (Fed. Cir. 2006); *see also In re Applied Materials, Inc.*, 692 F.3d 1289, 1295 (Fed. Cir. 2012) (same); *In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003) (same); *In re Geisler*, 116 F.3d 1465, 1469 (Fed. Cir. 1997) (same); *In re Woodruff*, 919 F.2d 1575, 1577–78 (Fed. Cir. 1990) (same); *Tris Pharma, Inc. v. Actavis Labs.*

FL, Inc., 276 F. Supp. 3d 226, 252 (D. Del. 2017) (same), *vacated on other grounds*, 755 F. App'x 983 (Fed. Cir. 2019).

132. This *prima facie* case exists where there is “even a slight overlap in range.” *In re Peterson*, 315 F.3d at 1329; *see also, e.g., In re Geisler*, 116 F.3d at 1469 (claimed invention was rendered *prima facie* obvious by a prior art reference whose disclosed range (50–100 Angstroms) overlapped the claimed range (100–600 Angstroms)); *In re Woodruff*, 919 F.2d at 1576–77 (claimed invention was rendered obvious by a prior art reference whose disclosed range of “about 1–5%” carbon monoxide abutted the claimed range of “more than 5% to about 25%” carbon monoxide).

133. Even where the claimed range and the prior art range do not overlap, “a *prima facie* case of obviousness exists when the claimed range and the prior art range . . . are close enough such that one skilled in the art would have expected them to have the same properties.” *In re Peterson*, 315 F.3d at 1329.

134. “[T]he existence of overlapping or encompassing ranges shifts the burden to the applicant to show that his invention would not have been obvious.” *In re Peterson*, 315 F.3d at 1329–30; *see also, e.g., Tris Pharma*, 276 F. Supp. 2d at 253; *Warner Chilcott Co. v. Teva Pharm. USA, Inc.*, 89 F. Supp. 3d 641, 655–56 (D.N.J. 2015), *aff'd*, 642 F. App'x 996 (Fed. Cir. 2016). In such cases, “the burden of production falls upon the patentee to come forward with evidence that (1) the

prior art taught away from the claimed invention; (2) there were new and unexpected results relative to the prior art; or (3) there are other pertinent secondary considerations.” *Allergan, Inc. v. Sandoz, Inc.*, 796 F.3d 1293, 1304–05 (Fed. Cir. 2015); *accord, Galderma*, 737 F.3d at 738 (citing *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 719 F.3d 1346, 1352–54 (Fed. Cir. 2013)).

135. “[T]he disclosure in the prior art of overlapping pH ranges would have provided sufficient motivation to optimize the pH, and it was not inventive to do so.” *Tris Pharma*, 276 F. Supp. 3d at 253.

136. Patentability is not imparted where the inventor did no more than engage in routine experimentation. *See Merck & Co. v. Biocraft Labs., Inc.*, 874 F.2d 804, 809 (Fed. Cir. 1989) (“The evidence at trial showed that, though requiring time and care, the experimentation needed to arrive at the claimed dosages was nothing more than routine.”); *see also Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 335 (1945) (“Reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put into the last opening in a jig-saw puzzle. It is not invention.”).

137. Furthermore, “[w]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *Genentech, Inc. v. Hospira, Inc.*, 946 F.3d 1333, 1341–42 (Fed. Cir. 2020) (quoting *In re Applied Materials*, 692 F.3d at 1295); *In re Aller*,

220 F.2d 454, 456 (C.C.P.A. 1955) (same); *In re Geisler*, 116 F.3d at 1470 (same); *see also In re Peterson*, 315 F.3d at 1330 (“The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.”).

138. An obviousness determination requires both “the existence of a motivation to combine elements from different prior art references” and that “a skilled artisan would have perceived a reasonable expectation of success in making the invention via that combination.” *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006); *Merck & Co.*, 874 F.2d at 809 (explaining that a reasonable expectation of success does not require absolute predictability or certainty).

139. “Motivation to combine may be found in many different places and forms.” *Allergan, Inc. v. Sandoz Inc.*, 726 F.3d 1286, 1292 (Fed. Cir. 2013). The motivation to combine does not have to be explicitly stated in the prior art. *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1290 (Fed. Cir. 2006) (“[T]he teaching, motivation, or suggestion may be implicit from the prior art as a whole, rather than expressly stated in the references.” (citation omitted)); *see also Anacor Pharm., Inc. v. Iancu*, 889 F.3d 1372, 1385 (Fed. Cir. 2018) (“[T]he greater the structural similarity between the compounds, the greater the motivation to combine and reasonable expectation of success.”).

140. When determining obviousness, a court is “not limited to the same motivation that may have motivated the inventors.” *PAR Pharm., Inc. v. TWI Pharm., Inc.*, 773 F.3d 1186, 1197 (Fed. Cir. 2014); *see also Alcon Research, Ltd. v. Apotex Inc.*, 687 F.3d 1362, 1368 (Fed. Cir. 2012) (“We have repeatedly held that the motivation to modify a prior art reference to arrive at the claimed invention need not be the same motivation that the patentee had.”). In that vein, testimony of an expert witness regarding knowledge of a person of skill in the art at the time of invention “is pertinent to [the] evaluation of a prima facie case of obviousness.” *Alza*, 464 F.3d at 1294.

141. Where the prior art would make a technique or combination obvious to try, it is generally obvious, unless the prior art did no more than make it obvious to vary all parameters, with no narrowing of the possibilities, or gave no guidance to a likely solution. *See Bayer Schering Pharm. AG v. Barr Labs, Inc.*, 575 F.3d 1341, 1347 (Fed. Cir. 2009) (noting that an invention is generally obvious to try unless an inventor “would have had to try all possibilities in a field unreduced by direction of the prior art” or the “prior art does not guide an inventor toward a particular solution”). The Supreme Court has explained that:

When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common

sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.

KSR, 550 U.S. at 421.

142. To “determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue,” a court should “look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art.” *KSR*, 550 U.S. at 418. A patent may be obvious if, *inter alia*, there was a “known problem for which there was an obvious solution encompassed by the patent’s claims” or the combination of the patent’s claims was “obvious to try.” *Id.* at 419–421.

143. Courts may “find a motivation to combine prior art references in the nature of the problem to be solved.” *Tokai Corp. v. Easton Enters., Inc.*, 632 F.3d 1358, 1371 (Fed. Cir. 2011) (quoting *Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1276 (Fed. Cir. 2004)). “[M]otivation to combine may be found explicitly or implicitly in market forces; design incentives; the ‘interrelated teachings of multiple patents’; ‘any need or problem known in the field of endeavor at the time of invention and addressed by the patent’; and the background knowledge, creativity, and common sense of the person of ordinary skill.” *Plantronics, Inc. v. Aliph, Inc.*, 724 F.3d 1343, 1354 (Fed. Cir. 2013).

144. “Obviousness requires a showing that ‘a skilled artisan would have perceived a reasonable expectation of success in making the invention in light of the prior art.’” *AstraZeneca LP v. Breath Ltd.*, 603 F. App’x 999, 1002 (Fed. Cir. 2015) (quoting *Amgen Inc. v. F. Hoffman–La Roche Ltd.*, 580 F.3d 1340, 1362 (Fed. Cir. 2009)). There need not be a “guarantee” of success. *Id.* (quoting *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364 (Fed. Cir. 2007)); *see also Medichem*, 437 F.3d at 1165 (“Obviousness does not require absolute predictability of success” (citation omitted)). To that end, “obviousness cannot be avoided simply by a showing of some degree of unpredictability in the art” *Pfizer*, 480 F.3d at 1364 (Fed. Cir. 2007); *see also Warner Chilcott Co., LLC v. Teva Pharm. USA, Inc.*, 594 F. App’x 630, 635–36 (Fed. Cir. 2014) (“[T]he record shows that there would have been a reasonable expectation of success in pursuing the 150 mg monthly dose . . . [even though] the highest single dose of risedronate that had actually been tested in a patient was 50 mg.”); *In re Corkill*, 771 F.2d 1496, 1500 (Fed. Cir. 1985) (“Although [the inventor] declared that it cannot be predicted how any candidate will work in a detergent composition, but that it must be tested, this does not overcome [the prior art’s] teaching that hydrated zeolites will work.”); *Hospira, Inc. v. Amneal Pharms., LLC*, 285 F. Supp. 3d 776, 784, 794 (D. Del. 2018) (noting that, as to a reasonable expectation of success, “that ‘expectation of success need only be reasonable, not absolute’” and further stating that “Plaintiff’s assertion that the

requirement for testing every potential configuration counsels against finding a reasonable expectation of success improperly equates a reasonable expectation with absolute certainty”).

145. Although the doctrine of inherency was “originally rooted in anticipation,” the Federal Circuit has recognized that “inherency may supply a missing claim limitation in an obviousness analysis.” *PAR Pharm.*, 773 F.3d at 1194–95 (collecting cases); *see also Acorda Therapeutics, Inc. v. Roxane Labs., Inc.*, 903 F.3d 1310, 1328 (Fed. Cir. 2018) (affirming district court’s “determination that claim limitations relating to pharmacokinetics—i.e., achieving 4-AP serum levels of 15–35 ng/ml—are inherent in the claimed invention and therefore obvious”); *In re Huai-Hung Kao*, 639 F.3d 1057, 1072 (Fed. Cir. 2011) (affirming the BPAI’s finding of inherency where “the only claim element not expressly disclosed in the prior art was the previously-unknown, yet inherent, food-effect property”); *In re Kubin*, 561 F.3d 1351, 1357 (Fed. Cir. 2009) (upholding the BPAI’s obviousness determination where, “[e]ven if no prior art of record explicitly discusses the ‘wherein the polypeptide binds CD48’ aspect of claim 73, the Kubin–Goodwin application itself instructs that CD48 binding is not an additional requirement imposed by the claims on the NAIL protein, but rather a property necessarily present in NAIL”). Where a claim limitation is inherent in the prior art, “there is no question

of a reasonable expectation of success in achieving it.” *Hospira, Inc. v. Fresenius Kabi USA, LLC*, 946 F.3d 1322, 1332 (Fed. Cir. 2020).

D. Rebuttal To *Prima Facie* Obviousness

1. Criticality

146. “When an applicant seeks to overcome a prima facie case of obviousness by showing improved performance in a range that is within or overlaps with a range disclosed in the prior art, the applicant must show that the [claimed] range is *critical*, generally by showing that the claimed range achieves unexpected results relative to the prior art range.” *In re Patel*, 566 F. App’x 1005, 1011 (Fed. Cir. 2014) (quotation omitted); *see also In re Geisler*, 116 F.3d 1465, 1470 (Fed. Cir. 1997) (“Only if the ‘results of optimizing a variable’ are ‘unexpectedly good’ can a patent be obtained for the claimed critical range.” (citations omitted)).

147. When considering criticality, courts look to “whether ‘the claimed invention exhibits some superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected.’” *Forest Labs., LLC v. Sigmapharm Labs., LLC*, 918 F.3d 928, 937 (Fed. Cir. 2019) (quoting *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995)); *accord Procter & Gamble, Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 994 (Fed. Cir. 2009) (citations omitted).

148. “[I]n order to properly evaluate whether a superior property was unexpected” for criticality, the Court must consider “what properties were

expected.” *Cf. Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1371 (Fed. Cir. 2007); *see also In re Mageli*, 470 F.2d 1380, 1384–85 (C.C.P.A. 1973) (“Unobviousness, however, cannot be predicated on superiority alone. Obviousness depends on what those skilled in the art would *expect*.” (emphasis in original)); *Aventis Pharma S.A. v. Hospira, Inc.*, 743 F. Supp. 2d 305, 348 (D. Del. 2010) (“To show unexpected benefits, the patent owner must first show ‘what properties were expected.’” (citation omitted)), *aff’d*, 675 F.3d 1324 (Fed. Cir. 2012). There can be no showing of unexpected results where a patentee provides no evidence of what a POSA would have expected. *Pfizer*, 480 F.3d at 1371 (“Here, Pfizer’s evidence must fail because the record is devoid of any evidence of what the skilled artisan would have expected. We will not simply presume that the skilled artisan would have expected that amlodipine besylate would have the same characteristics as amlodipine maleate, because as Pfizer asserts, its properties are not absolutely predictable.”).

149. In order to demonstrate criticality, it is insufficient to merely demonstrate a difference in degree. Rather, the patentee must demonstrate a difference in kind. *Warner Chilcott Co. v. Teva Pharm. USA, Inc.*, 89 F. Supp. 3d 641, 674 (D.N.J. 2015) (citation omitted), *aff’d*, 642 F. App’x 996 (Fed. Cir. 2016) (“But where selection of the claimed amount within the prior art range results in ‘only a difference in degree from the prior art results,’ the claimed amount is not critical.”); *Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 739 (Fed. Cir.

2013); *see also Bristol Myers Squibb Co. v. Teva Pharm. USA, Inc.*, 752 F.3d 967, 977 (Fed. Cir. 2014) (“While a ‘marked superiority’ in an expected property may be enough in some circumstances to render a compound patentable, a ‘mere difference in degree’ is insufficient And ‘differences in degree’ of a known and expected property are not as persuasive in rebutting obviousness as differences in ‘kind’ –i.e., a new property dissimilar to the known property.” (citations omitted)). “Results which differ by percentages are differences in degree rather than kind, where the modification of the percentage is within the capabilities of one skilled in the art at the time.” *Galderma*, 737 F.3d at 739; *see also In re Merck & Co.*, 800 F.2d 1091, 1099 (Fed. Cir. 1986) (a purported improvement in a known property is not unexpected unless there was an “appreciable degree” of improvement). Accordingly, courts must “evaluate the significance and ‘kind’ of expected results along with the unexpected results.” *Bristol Myers Squibb*, 752 F.3d at 977 (citations omitted).

150. Proving criticality “requires more than a modest deviation from what was disclosed in the prior art.” *Allergan Inc. v. Teva Pharm. USA, Inc.*, No. 15-cv-1455-WCB, 2017 WL 4803941, at *46 (E.D. Tex. Oct. 16, 2017) (Bryson, J.).

151. For there to be a showing of criticality, the results must be truly unexpected and not the product of the desire of a person of ordinary skill to achieve the optimum value of performance for a known range. *See In re Peterson*, 315 F.3d

1325, 1330 (Fed. Cir. 2003) (“The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages. We therefore conclude that a prior art reference that discloses a range encompassing a somewhat narrower claimed range is sufficient to establish a *prima facie* case of obviousness.”); *see also In re Boesch*, 617 F.2d 272, 276 (C.C.P.A. 1980) (“[D]iscovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art.” (citations omitted)). Further, the superior result must rise to a significant enough level where it can be characterized as being “a new and unexpected result which is different in kind and not merely in degree from the results of the prior art.” *In re Huang*, 100 F.3d 135, 139 (Fed. Cir. 1996) (citation omitted).

152. To assess criticality, one must compare the ***claimed invention*** to the prior art, rather than a narrower embodiment thereof. *In re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir. 1990) (“The only test results presented by Woodruff are the results reported by Mr. Bell, comparing Woodruff’s claimed invention to the commercial embodiment of McGill’s method. While Woodruff’s invention certainly showed superior fungi-inhibiting effect in these tests, the critical comparison is not with the commercial embodiment of McGill’s invention, but with the method taught in his patent.”). Further, “there is no requirement that the closest prior art be

commercialized.” *Trs. of Columbia Univ. v. Illumina, Inc.*, 620 F. App’x 916, 932 (Fed. Cir. 2015); *see also In re Merchant*, 575 F.2d 865, 869 (CCPA 1978) (“In *In re Wright* . . . , failure of a particular reference to constitute ‘the commercial standard’ did not diminish its position as the closest prior art.” (internal citation omitted)); *In re Chupp*, 816 F.2d 643, 644 (Fed. Cir. 1987) (“To rebut the *prima facie* case of obviousness, Chupp submitted a declaration discussing the results of tests comparing the herbicidal activity of the claimed compound with that of the closest prior art compounds and with two commercial herbicides.” (emphasis added)).

153. The closest prior art can be a patent or publication. *See, e.g., In re Huston*, 308 F.3d 1267, 1281 n.9 (Fed. Cir. 2002) (sustaining the Board’s obviousness rejection and discussing the ways in which it relied “on the Paul reference [U.S. Patent No. 5,524,081] (cited by the Board itself as the ‘closest prior art’)” for its analysis); *Procter & Gamble Co. v. Paragon Trade Brands, Inc.*, 989 F. Supp. 547, 595 (D. Del. 1997) (holding the asserted patent obvious and noting that “[t]he Court finds particularly persuasive the fact that the Enloe patent, the closest prior art reference, expressly teaches away from the use of liquid impermeable materials for the BLC”).

154. In order to establish criticality, the alleged criticality must be commensurate in scope with the claims. *E.I. DuPont de Nemours & Co. v. Synvina*

C.V., 904 F.3d 996, 1012 (Fed. Cir. 2018); *see also Genetics Inst., LLC v. Novartis Vaccines & Diagnostics, Inc.*, 655 F.3d 1291, 1308 (Fed. Cir. 2011). This means that the evidence cannot be “plainly disproportionate to the scope of the claim.” *Id.*; *see, e.g., In re Harris*, 409 F.3d 1339, 1344 (Fed. Cir. 2005) (affirming Board’s finding that showing of unexpected results was not commensurate in scope with the claims where “the elemental composition of CMSX®-486 [the applicant’s commercial embodiment relied on to show unexpected results] is at or near the midpoint of the claimed range”); *Peterson*, 315 F.3d at 1331 (affirming obviousness finding where patentee claimed an alloy with 1–3% rhenium, but presented unexpected results only for 2% rhenium, and evidence suggested that 3% rhenium possessed inferior properties); *In re Grasselli*, 713 F.2d 731, 743 (Fed. Cir. 1983) (concluding that unexpected results “limited to sodium only” were not commensurate in scope with claims to a catalyst having “an alkali metal”); *In re Greenfield*, 571 F.2d 1185, 1189 (C.C.P.A. 1978) (affirming obviousness finding for a genus containing “several hundred compounds” where unexpected results were proved for “only one” such compound).

155. “[A] claimed amount [is] not critical where specification of patent disclosed that amounts . . . outside the claimed amount were also effective.” *Tris Pharma, Inc. v. Actavis Labs. FL, Inc.*, 276 F. Supp. 3d 226, 254 (D. Del. 2017) (citing *Warner Chilcott*, 89 F. Supp. 3d at 655–56), *vacated on other grounds*, 755

F. App’x 983 (Fed. Cir. 2019); *see also, e.g., id.* (“The patents-in-suit make clear that ‘the product is most stable at pH between 3.5 and 5.0. . . . Thus, there is nothing critical about the narrower range of 4 to 4.5.’”); *Warner Chilcott*, 89 F. Supp. 3d at 655–56 (“Thus, the patents assert that the disclosed range of 75 mg to 250 mg EDTA will work effectively with risedronate sodium. It does not indicate that any particular level of EDTA is critical for each type of bisphosphonate.”), *aff’d*, 642 F. App’x 996 (Fed. Cir. 2016) (“Moreover, in view of the broad disclosures in the specification providing embodiments with varying amounts of EDTA, and nothing in the asserted claims teaching one of skill in the art that or how only the specific 100 mg amount produces pharmaceutically effective absorption, Warner Chilcott failed to show the criticality of the claimed amount.”).

156. Differences of a specific condition or parameter will generally not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such specified condition or parameter is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456 (C.C.P.A. 1955) (claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of

100°C and an acid concentration of 10%.); *In re Hoeschele*, 406 F.2d 1403, 1406 (C.C.P.A. 1969) (claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions).

157. “A recognition in the prior art that a property is affected by the variable is sufficient to find the variable result-effective.” *E.I. DuPont de Nemours*, 904 F.3d at 1006. Merely optimizing a result-effective variable does not render a claimed invention non-obvious because “discovery of an optimum value of a result effective variable . . . is ordinarily within the skill of the art.” *See id.*; *In re Applied Materials, Inc.*, 692 F.3d 1289, 1297 (Fed. Cir. 2012).

2. Teaching Away

158. “Although a reference that teaches away is a significant factor to be considered in determining unobviousness, the nature of the teaching is highly relevant, and must be weighed in substance.” *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). “A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use.” *Id.*; *see also Santarus, Inc. v. Par Pharm., Inc.*, 694 F.3d 1344, 1356 (Fed. Cir. 2012) (prior art did not teach away when it merely characterized alleged inventive feature as being the “second best choice”).

159. A reference teaches away “when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.” *Gator Tail, LLC. v. Mud Buddy, LLC*, 618 F. App’x 992, 998–99 (Fed. Cir. 2015) (quoting *In re Gurley*, 27 F.3d at 553). Indeed, the **only** relevant inquiry is whether a person of ordinary skill would have considered the prior art to teach away; other reasons not to make the claimed invention (such as economic considerations) are irrelevant. See *In re Farrenkopf*, 713 F.2d 714, 718 (Fed. Cir. 1983) (“That a given combination would not be made by businessmen for economic reasons does not mean that persons skilled in the art would not make the combination because of some technological incompatibility. Only the latter fact would be relevant.”).

160. There is no “teaching away” if the reference “merely expresses a general preference for an alternative invention but does not ‘criticize, discredit, or otherwise discourage’ investigation into the invention claimed.” *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1327 (Fed. Cir. 2009) (citation omitted). Nor does silence or a lack of certainty imply teaching away. *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 964 (Fed. Cir. 2014) (addressing silence); *Warner Chilcott Co. v. Teva Pharm. USA, Inc.*, 89 F. Supp. 3d 641, 667 n. 24 (D.N.J. 2015), *aff’d*, 642 F. App’x 996 (Fed. Cir. 2016) (addressing uncertainty).

161. A reference does not teach away if it does not disclose the claimed invention. *See, e.g., Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 738 (Fed. Cir. 2013) (“Neither of these articles mentions 0.3% adapalene compositions, nor do they expressly teach away from the claimed invention. The district court inferred that these references taught away from a further tripling of the adapalene concentration. We cannot agree with this inference.”).

162. Similarly, “[a] teaching that a composition may be optimal or standard does not criticize, discredit, or otherwise discourage investigation into other compositions.” *Galderma*, 737 F.3d at 739; *see also SightSound Techs., LLC v. Apple Inc.*, 809 F.3d 1307, 1320 (Fed. Cir. 2015) (“‘[M]ere disclosure of more than one alternative’ does not amount to teaching away from one of the alternatives where the reference does not ‘criticize, discredit, or otherwise discourage the solution claimed.’” (citation omitted)).

163. Moreover, the mere existence of drawbacks does not render the claimed invention non-obvious; the benefits and drawbacks of the claimed invention must be weighed accordingly. *See Hoffman-La Roche Inc. v. Apotex Inc.*, 748 F.3d 1326, 1333 (Fed. Cir. 2014) (“A higher frequency of diarrhea does not necessarily teach away . . . modest gastrointestinal side effects must be weighed in light of the benefits of the drug.”); *Galderma*, 737 F.3d at 738–39 (“These articles show increased side effects associated with 0.1% adapalene as compared to 0.03% adapalene, yet they

failed to discourage even the use of 0.1% adapalene. . . . [N]or do these articles indicate in any way that the side effects would be serious enough to dissuade the development of a 0.3% adapalene product.”); *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) (“[A] given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate motivation to combine.”).

164. “Evidence concerning whether the prior art teaches away from a given invention must relate to and be commensurate in scope with the ultimate claims at issue.” *Idemitsu Kosan Co. v. SFC Co.*, 870 F.3d 1376, 1381 (Fed. Cir. 2017).

E. Written Description and Enablement

165. Under 35 U.S.C. § 112(a), the specification of a patent

shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same
. . . .

In other words, this paragraph sets forth two distinct requirements: (1) that the specification describe the invention in clear and concise terms (the written description requirement) and; (2) that the specification enables any person skilled in the art to practice the invention (the enablement requirement). *See Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1344 (Fed. Cir. 2010) (*en banc*) (setting forth

the distinct requirements of § 112, first paragraph, which is substantially identical to AIA § 112(a)).

166. While written description and enablement overlap in some regards, they are two distinct requirements. As the Federal Circuit stated in *Ariad*:

Perhaps there is little difference in some fields between describing an invention and enabling one to make and use it, but that is not always true of certain inventions, ***including chemical and chemical-like inventions***. Thus, although written description and enablement often rise and fall together, requiring a written description of the invention plays a vital role in curtailing claims that do not require undue experimentation to make and use, and thus satisfy enablement, but that have not been invented, and thus cannot be described.

Id. at 1352 (emphasis added).

1. *Written Description*

167. “[A] patent can be held invalid for failure to meet the written description requirement, based solely on the language of the patent specification.” *Univ. Of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927 (Fed. Cir. 2004) (citing *PIN/NIP, Inc. v. Platte Chem. Co.*, 304 F.3d 1235 (Fed. Cir. 2002)).

168. The written description requirement requires that the specification “‘clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed.’ In other words, the test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” *Ariad, 5 Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010)

(*en banc*) (citation omitted); *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991) (“Although the applicant does not have to describe exactly the subject matter claimed, the description must clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed.” (internal quotation marks, brackets, and ellipses omitted)).

169. The test for written description “requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. Based on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed.” *Ariad*, 598 F.3d at 1351. Each and every claim limitation must find support in the specification. *See TurboCare Div. of Demag Delaval Turbomachinery Corp. v. Gen. Elec. Co.*, 264 F.3d 1111, 1118 (Fed. Cir. 2001) (“The written description requirement and its corollary, the new matter prohibition of 35 U.S.C. § 132, both serve to ensure that the patent applicant was in full possession of the claimed subject matter on the application filing date.”).

170. Merely reciting the claim language in the specification is insufficient to show possession. *See Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 968–69 (Fed. Cir. 2002) (“[T]he fact that [a claim] appears as an original claim or in the specification does not save it. A claim does not become more descriptive by its repetition”). The specification must describe the claim “as an integrated whole

rather than as a collection of independent limitations.” *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1349 (Fed. Cir. 2013); accord, *Purdue Pharma L.P. v. Recro Tech., LLC*, 694 F. App’x 794, 797–98 (Fed. Cir. 2017). In other words, where the specification “merely renders the invention obvious,” the written description requirement is not satisfied. *Purdue Pharma*, 694 F. App’x at 796 (quoting *Ariad*, 598 F.3d at 1352); see also *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997) (“One shows that one is ‘in possession’ of *the invention* by describing *the invention*, with all its claimed limitations, not that which makes it obvious.” (emphasis in original)).

171. Describing a single embodiment or species in the specification may be insufficient if it is at all unclear that possession of the one embodiment inherently indicates possession of the whole range or genus. See *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1346 (Fed. Cir. 2005) (“[A] patentee cannot always satisfy the requirements of section 112, in supporting expansive claim language, merely by clearly describing one embodiment of the thing claimed.”); see also *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 433 F.3d 1373, 1375 (Fed. Cir. 2006) (“But merely calling an embodiment ‘preferred,’ when there are no others, does not entitle one to claims broader than the disclosure.”).

172. Indeed, “[i]t is well settled that claims in an application which are broader than the applicant’s disclosure are not allowable.” *In re Sus*, 306 F.2d 494,

505 (C.C.P.A. 1962) (quoting *In re Moore*, 155 F.2d 379, 382 (C.C.P.A. 1946); *see also ICU Med., Inc. v. Alaris Med. Sys., Inc.*, 558 F.3d 1368, 1378 (Fed. Cir. 2009) (“ICU’s asserted spikeless claims are broader than its asserted spike claims because they do not include a spike limitation; these spikeless claims thus refer to medical valves generically—covering those valves that operate with a spike and those that operate without a spike. But the specification describes only medical valves with spikes. . . . We reject ICU’s contention that the figures and descriptions that include spikes somehow demonstrate that the inventor possessed a medical valve that operated without a spike.”); *In re Alonso*, 545 F.3d 1015, 1021 (Fed. Cir. 2008) (no written description where specification disclosed only a single embodiment, finding the single embodiment “cannot be said to be representative of a densely populated genus”); *Ariad*, 598 F.3d at 1353 (finding claims invalid for written description because they “cover[ed] any compound later actually invented and determined to fall within the claim’s functional boundaries—leaving it to the pharmaceutical industry to complete an unfinished invention”).

173. *Pernix Ireland Pain DAC v. Alvogen Malta Operations* is instructive. There, the claims at issue “read on all oral dosage units comprising extended-release hydrocodone in which hydrocodone is the only active ingredient,” but the “specification disclose[d] only one formulation that was found to satisfy all the limitations of any of the claims, including the functional limitations.” 323 F. Supp.

3d 566, 618–19 (D. Del. 2018) (Bryson, J.), *aff’d on other grounds*, 945 F.3d 1184 (Fed. Cir. 2019); *see id.* at 624 (“But all that evidence shows is that that the inventors had possession of a single species. It does not show that they had possession of the broad genus covered by the claims.”). The court found that the specification, which disclosed “only a single embodiment within the broad scope of the claims,” was insufficient to provide written description support because the result claimed by the patent method “depend[ed] entirely on whether the particular formulation function[ed] in the manner recited in the claims.” *Id.* at 624–26. Indeed, the court found that because “testing results would be fundamental to determining which formulations would satisfy the asserted claims, . . . in the absence of such testing data, the inventors cannot be said to have possessed the full scope of the claimed invention.” *Id.* at 628.

174. Finally, where a POSA would have to engage in an “iterative, trial-and-error process” to determine whether a given formulation worked for its intended purpose, the claims are invalid for lack of written description. *See, e.g., MorphoSys AG v. Janssen Biotech, Inc.*, 358 F. Supp. 3d 354, 371 (D. Del. 2019); *see also Pernix*, 323 F. Supp. 3d at 628 (“All that the specification discloses is that one such formulation will work for that purpose. Whether any others will work, and which they are, would depend entirely on testing, and thus cannot be said to have been within the scope of what the patentees invented.”).

2. Enablement

175. By statute, a patent must “enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use” the claimed invention. 35 U.S.C. § 112(a). “To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.” *ALZA Corp. v. Andrx Pharm., LLC*, 603 F.3d 935, 940 (Fed. Cir. 2010) (internal quotation marks omitted). “[A] patentee chooses broad claim language at the peril of losing any claim that cannot be enabled across its full scope of coverage.” *MagSil Corp. v. Hitachi Glob. StorageTechs., Inc.*, 687 F.3d 1377, 1381 (Fed. Cir. 2012); *see also Par Pharma., Inc. v. TWi Pharm., Inc.*, 120 F. Supp. 3d 468, 475–79 (D. Md. 2015) (invalidating claims because they were broad enough to read on inoperative particle sizes), *aff’d without opinion*, 624 F. App’x 756 (Fed. Cir. 2015).

176. It is well settled that the “full scope of the claimed invention must be enabled.” *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 999 (Fed. Cir. 2008); *id.* (“[a] patentee who chooses broad claim language must make sure the broad claims are fully enabled”); *see also Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1379–80 (Fed. Cir. 2007) (“[I]n this case, the asserted claims read on, and the full scope of the claimed invention includes, an injector system with and without a pressure jacket. There must be ‘reasonable enablement of the scope of the range’

which, in this case, includes both injector systems with and without a pressure jacket. The specification's reference that teaches away from an injector system with a disposable syringe without a pressure jacket, . . . supports the district court's conclusion that the specification fails to fulfill the enablement requirement of § 112"); *Pharm. Res., Inc. v. Roxane Labs., Inc.*, Civ. No. 03–3357(DRD), 2006 WL 3231427, at *13 (D.N.J. Nov. 8, 2006) ("The claims encompass every possible megestrol acetate flocculated suspension made with any surfactant and one or more of the listed wetting agents, with the exception of the combination that Atzinger recommended. Par's common specification fails to provide an enabling disclosure of similar scope."), *aff'd*, 253 F. App'x 26 (Fed. Cir. 2007).

177. Claims are enabled when they may be practiced without undue experimentation. *ALZA*, 603 F.3d at at 940. The factors to be considered in determining whether a disclosure would require undue experimentation include: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

178. Breadth alone can be the basis for finding a lack of enablement. *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1213–14 (Fed. Cir. 1991) (affirming

district court's invalidation under Section 112 based on breadth alone where Amgen claimed every possible analog of a gene containing about 4,000 nucleotides with details for preparing only a few EPO analog genes).

179. “Undue experimentation is evaluated from the vantage point of those experienced in the field of the invention.” *Impax Labs., Inc. v. Aventis Pharm. Inc.*, 496 F. Supp. 2d 428, 432 (D. Del. 2007), *aff'd*, 545 F.3d 1312 (Fed. Cir. 2008). Some “experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.” *Wands*, 858 F.2d at 737.

180. A patent with “a complete absence of data supporting the statements which set forth the desired results of the claimed invention” fails for lack of enablement. *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1323–24 (Fed. Cir. 2005) (stating that patentee needed to provide experimental proof that the patented invention was operable); *Petito v. Puritan's Pride, Inc.*, 35 F. Supp. 3d 494, 504 (S.D.N.Y. 2014) (quoting *Rasmusson* and finding a patent not enabled because the claims were “not supported by any experimental results” and the specification failed to “describe[] test results or other substantiating evidence”).

181. In the absence of sufficient test results, the mere fact that an assertion of use may be tested or a method carried out by a POSA also is insufficient. For example, in *Rasmusson* the Federal Circuit rejected the assertion “that the

specifications of the respective applications are enabling because a person of ordinary skill in the art could perform the steps of the disclosed method without the need for any experimentation.” *Rasmusson*, 413 F.3d at 1322; *see also Auto. Techs. Int’l, Inc. v. BMW of N. Am., Inc.*, 501 F.3d 1274, 1285 (Fed. Cir. 2007) (finding claims “including both mechanical and electronic side impact sensors” lacked enablement where there was “[d]isclosure of only mechanical side impact sensors”); *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1256 (Fed. Cir. 2004) (“Here, the scope of the claim includes not only murine but also chimeric antibodies. While Chiron’s applications certainly enable murine antibodies, they do not enable chimeric antibodies.”); *cf.*, *Pharm. Res.*, 253 F. App’x at 31 (agreeing with district court that “numerous unsuccessful attempts by Par to practice subject matter within the scope of the claims” supported a determination of no enablement).

182. Furthermore, “[e]nablement is determined as of the effective filing date of the patent’s application.” *ALZA*, 603 F.3d at 940. That is, “the enabling disclosure must appear in the specification at the time of filing.” *MagSil*, 687 F.3d at 1382. A patentee cannot rely on post-filing experimental data to establish utility. *In re ’318 Patent Infringement Litig.*, 583 F.3d 1317, 1325 (Fed. Cir. 2009) (affirming district court finding that test results not available at the time of the patent application could not be used to establish enablement).

183. A patent cannot be both non-obvious and enabled if the patentee relies on the prior art to establish enablement. *See, e.g., In re '318 Patent Infringement Litig.*, 578 F. Supp. 2d 711, 736 (D. Del. 2008) (“Put another way, since plaintiffs rely exclusively on the prior art to establish enablement, the court agrees with defendants that the ’318 patent cannot both be non-obvious and enabled.”).

3. *Indefiniteness*

184. Under 35 U.S.C. § 112(b), “[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.” This is referred to as the “definiteness” requirement, which mandates that “the boundaries of the claim, as construed by the court, must be discernible to a skilled artisan based on the language of the claim, the specification, and the prosecution history, as well as her knowledge of the relevant field of art.” *Power-One, Inc. v. Artesyn Techs., Inc.*, 599 F.3d 1343, 1350 (Fed. Cir. 2010); *see also Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014) (“[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, ***with reasonable certainty***, those skilled in the art about the scope of the invention.” (emphasis added)).

185. Whether the claims satisfy the definiteness requirement is a question of law. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1341 (Fed. Cir. 2015).

186. To meet the definiteness requirement, the claims must provide “clear notice” to the public as to the boundaries of the invention. *Nautilus*, 572 U.S. at 909.

187. Although the “public-notice function” allows for “some modicum of uncertainty” in light of the inherent limitations of language, the patent and prosecution history must still “disclose a single known approach or establish that, where multiple known approaches exist, a person having ordinary skill in the art would know which approach to select.” *Dow Chem. Co. v. Nova Chems. Corp. (Can.)*, 803 F.3d 620, 630 (Fed. Cir. 2015) (citations omitted); *see also Nautilus*, 572 U.S. at 909.

188. In sum, a claim that is definite will “provide objective boundaries for those of skill in the art.” *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1371 (Fed. Cir. 2014). “[I]t is not enough . . . to identify *some standard* for measuring the scope of the phrase. The Supreme Court explained that a patent does not satisfy the definiteness requirement of § 112 merely because a court can ascribe *some* meaning to a patent’s claims.” *Id.* at 1370–71 (internal citations and quotation marks omitted). If multiple methods are available to a POSA that would “lead[] to different results without guidance in the patent or the prosecution history as to which method should be used,” then the claim is indefinite. *Dow Chem.*, 803 F.3d at 634.

189. Although neither is inherently indefinite, this standard is particularly harsh to claims involving particular measurements or terms of degree. *See, e.g.,*

Berkheimer v. HP Inc., 881 F.3d 1360, 1363–64 (Fed. Cir. 2018) (finding the term “minimal redundancy” indefinite, as the “claim language is not reasonably clear as to what level of redundancy in the archive is acceptable”); *Teva*, 789 F.3d at 1341 (finding the term “molecular weight” indefinite because it did “not convey with reasonable certainty the measure of molecular weight to be used”).

V. REMEDIES

A. Injunctive Relief

190. Once the issue of infringement has been resolved, damages must be determined. Rarely are monetary damages awarded, as there is seldom a commercial ANDA product on the market. *See* 35 U.S.C. § 271(e)(4)(C).

191. Instead, where a patentee proves infringement, “the court shall order the effective date of any approval of the drug . . . involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed.” 35 U.S.C. § 271(e)(4)(A).

192. Furthermore, in some cases, injunctive relief “*may*” be warranted, 35 U.S.C. § 271(e)(4)(B) (emphasis added), but only if the patentee meets the traditional standard for obtaining a permanent injunction. *See Bayer Pharma AG v. Watson Labs., Inc.*, C.A. No. 12-1726-LPS, 2016 WL 7468172, at *2 (D. Del. Dec. 28, 2016) (“In order to obtain a permanent injunction [against an ANDA product], a party with a valid and infringed patent must show that the following factors favor

the requested relief: (i) the patent holder has suffered or will suffer irreparable injury or harm, (ii) legal remedies are inadequate to compensate that injury, (iii) balance of hardships, and (iv) the public interest.” (citing *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006))); *see also Alcon, Inc. v. Teva Pharm. USA, Inc.*, C.A. No. 06-234-SLR, 2010 WL 3081327, at *2 (D. Del. Aug. 5, 2010) (explaining that the prevailing patentee in ANDA case is not automatically entitled to a § 271(e)(4)(B) injunction but, instead, must demonstrate that the four traditional factors weigh in its favor).

B. Costs and Fees

193. Federal Rule of Civil Procedure 54 states “[u]nless a federal statute, these rules, or a court order provides otherwise, costs—other than attorney’s fees—should be allowed to the prevailing party.” Fed. R. Civ. P. 54(d)(1). To that end, 28 U.S.C. § 1920 permits judges or clerks to tax as costs the following:

(1) Fees of the clerk and marshal; (2) Fees for printed or electronically recorded transcripts necessarily obtained for use in this case; (3) Fees and disbursements for printing and witnesses; (4) Fees for exemplification and the costs of making copies of any materials where the copies are necessarily obtained for use in the case; (5) Docket fees under [28 U.S.C. § 1923]; and (6) Compensation of court appointed experts, compensation of interpreters, and salaries, fees, expenses, and costs of special interpretation services under [28 U.S.C. § 1828].

See also D. Del. LR 54.1.

C. Attorneys' Fees

194. In exceptional cases, a court may award reasonable attorneys' fees to the prevailing party. 35 U.S.C. § 285. The decision to award attorneys' fees is based on a two-step inquiry. *Interspiro USA, Inc. v. Figgie Int'l Inc.*, 18 F.3d 927, 933 (Fed. Cir. 1994).

195. First, the court must evaluate whether the case is exceptional. *Interspiro*, 18 F.3d at 933. A case is exceptional if it “stands out from others with respect to the substantive strength of a party’s litigation position (considering both the governing law and the facts of the case) or the unreasonable manner in which the case was litigated.” *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 572 U.S. 545, 553 (2014). This determination is a “case-by-case exercise” to be made based on “the totality of the circumstances.” *Id.*

196. Second, the court must determine whether an award of attorneys' fees to the prevailing party is warranted. *Interspiro*, 18 F.3d at 933.

197. The burden of proof rests with the prevailing party, but there is no particular standard of proof or evidentiary burden; “[s]ection 285 demands a simple discretionary inquiry.” *Octane Fitness*, 572 U.S. at 557.

198. Moreover, prevailing on a claim of inequitable conduct often makes a case “exceptional,” leading potentially to an award of attorneys' fees under 35 U.S.C. § 285. *Therasense Inc. v. Becton Dickinson & Co.*, 649 F.3d 1276, 1289

EXHIBIT 5

(Fed. Cir. 2011); *see also, e.g., Regeneron Pharm., Inc. v. Merus N.V.*, No. 1:14-cv-01650-KBF, slip op. at 31–35 (S.D.N.Y. Mar. 26, 2018) (D.I. No. 468).

EXHIBIT 6

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

<p>PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC and ENDO PAR INNOVATION COMPANY, LLC,</p> <p>Plaintiffs,</p> <p>v.</p> <p>EAGLE PHARMACEUTICALS INC.,</p> <p>Defendant.</p>	<p>C.A. No. 18-cv-823-CFC</p> <p>[REDACTED]</p>
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JOINT LIST OF EXHIBITS

Parv. Eagle
23193
Ex. 6 PTO

Joint Trial Exhibit List

JTX#	PTX #	DTX#	Date	Bates Begin	Bates End	Description	Depo. Exh No.	Confidentiality
JTX-0001	PTX-0001	DTX-587	2017-06-27	PAR-VASO_0295299	PAR-VASO_0295377	Clean copy of United States Patent 9,687,526: Vasopressin Formulations for Use in Treatment of Hypotension		
JTX-0002	PTX-0002	DTX-522	2017-08-29	PAR-VASO_0295216	PAR-VASO_0295298	Clean copy of United States Patent 9,744,209: Vasopressin Formulations for Use in Treatment of Hypotension		
JTX-0003	PTX-0003	DTX-588	2017-09-05	PAR-VASO_0295378	PAR-VASO_0295459	Clean copy of United States Patent 9,750,785: Vasopressin Formulations for Use in Treatment of Hypotension		
JTX-0004	PTX-0004	DTX-002	2017-06-27	PAR-VASO_0000034	PAR-VASO_0000113	Certified copy of United States Patent 9,687,526: Vasopressin Formulations for Use in Treatment of Hypotension		
JTX-0005	PTX-0005	DTX-003	2017-08-29	PAR-VASO_0000114	PAR-VASO_0000197	Certified copy of United States Patent 9,744,209: Vasopressin Formulations for Use in Treatment of Hypotension		
JTX-0006	PTX-0006	DTX-005	2017-09-05	PAR-VASO_0000232	PAR-VASO_0000314	Certified copy of United States Patent 9,750,785: Vasopressin Formulations for Use in Treatment of Hypotension		
JTX-0007	PTX-0007	DTX-008	2016-10-10	PAR-VASO_0002629	PAR-VASO_0005399	Certified copy of File Wrapper for United States Patent 9,687,526		
JTX-0008	PTX-0008	DTX-009	2017-08-29	PAR-VASO_0005400	PAR-VASO_0006452	Certified copy of File Wrapper for United States Patent 9,744,209		
JTX-0009	PTX-0009	DTX-011	2017-09-05	PAR-VASO_0009319	PAR-VASO_0010365	Certified copy of File Wrapper for United States Patent 9,750,785		
JTX-0010	PTX-0010	DTX-015	2017-04-19	PAR-VASO_0108290	PAR-VASO_0108299	Certified Assignment Reel/Frame 042097.0331		
JTX-0011	PTX-0011	DTX-014	2016-10-26	PAR-VASO_0108300	PAR-VASO_0108307	Certified Assignment Reel/Frame 040491.0176		
JTX-0012	PTX-0012	DTX-019	2017-03-02	PAR-VASO_0108308	PAR-VASO_0108313	Certified Assignment Reel/Frame 041442.0453		
JTX-0013	PTX-0013	DTX-017	2017-03-02	PAR-VASO_0108321	PAR-VASO_0108326	Certified Assignment Reel/Frame 041442.0482		
JTX-0014	PTX-0014	DTX-016	2017-04-20	PAR-VASO_0108333	PAR-VASO_0108341	Certified Assignment Reel/Frame 042293.0855		
JTX-0015	PTX-0015	DTX-021	2017-06-08	PAR-VASO_0108342	PAR-VASO_0108373	Certified Assignment Reel/Frame 042743.0216		

EXHIBIT 7

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

<p>PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC and ENDO PAR INNOVATION COMPANY, LLC,</p> <p>Plaintiffs,</p> <p>v.</p> <p>EAGLE PHARMACEUTICALS INC.,</p> <p>Defendant.</p>	<p>C.A. No. 18-cv-823-CFC</p> <p>[REDACTED]</p>
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PLAINTIFFS' LIST OF EXHIBITS

Plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC (collectively "Plaintiffs") reserve their right to incorporate by reference into their Trial Exhibit List any exhibit listed by Defendant Eagle Pharmaceuticals Inc. ("Defendant") on Defendant's Trial Exhibit List. Plaintiffs reserve their right to amend, modify, or supplement their Trial Exhibit List throughout the balance of this case in response to case developments including but not limited to Defendant's Trial Exhibit List, Defendant's objections, and/or further streamlining of the case. Plaintiffs also reserve the right to supplement or modify their Trial Exhibit List in response to rulings by the Court (including on any motions) or upon settlement of any party. Plaintiffs also reserve their right to add demonstratives to their Trial Exhibit List. Plaintiffs agree to exchange demonstratives with Defendant in accordance with the procedures agreed upon by the parties in the Joint Pretrial Order.

EXHIBIT
23201

Par V. Eagle

Plaintiffs First Amended Exhibit List

PTX #	Date	Bates Begin	Bates End	Description	Depo. Exh No.	Objection(s)
PTX-0001	2017-06-27	PAR-VASO_0295299	PAR-VASO_0295377	Moved to JTX-0001		
PTX-0002	2017-08-29	PAR-VASO_0295216	PAR-VASO_0295298	Moved to JTX-0002		
PTX-0003	2017-09-05	PAR-VASO_0295378	PAR-VASO_0295459	Moved to JTX-0003		
PTX-0004	2017-06-27	PAR-VASO_0000034	PAR-VASO_0000113	Moved to JTX-0004		
PTX-0005	2017-08-29	PAR-VASO_0000114	PAR-VASO_0000197	Moved to JTX-0005		
PTX-0006	2017-09-05	PAR-VASO_0000232	PAR-VASO_0000314	Moved to JTX-0006		
PTX-0007	2016-10-10	PAR-VASO_0002629	PAR-VASO_0005399	Moved to JTX-0007		
PTX-0008	2017-08-29	PAR-VASO_0005400	PAR-VASO_0006452	Moved to JTX-0008		
PTX-0009	2017-09-05	PAR-VASO_0009319	PAR-VASO_0010365	Moved to JTX-0009		
PTX-0010	2017-04-19	PAR-VASO_0108290	PAR-VASO_0108299	Moved to JTX-0010		
PTX-0011	2016-10-26	PAR-VASO_0108300	PAR-VASO_0108307	Moved to JTX-0011		
PTX-0012	2017-03-02	PAR-VASO_0108308	PAR-VASO_0108313	Moved to JTX-0012		
PTX-0013	2017-03-02	PAR-VASO_0108321	PAR-VASO_0108326	Moved to JTX-0013		
PTX-0014	2017-04-20	PAR-VASO_0108333	PAR-VASO_0108341	Moved to JTX-0014		
PTX-0015	2017-06-08	PAR-VASO_0108342	PAR-VASO_0108373	Moved to JTX-0015		
PTX-0016	2018-02-05	AMRIVAS0004941	AMRIVAS0004946	OOS Report Confirmed Results for Unspecified Degradation Product for SVA002, SVA 003, 25C, Stability Samples	Romito Exhibit 40	H, R, 403, F, Dup
PTX-0017	2018-03-07	AMRIVAS0004941	AMRIVAS0004946	OOS Report Confirmed Results for Unspecified Degradation Product for SVA002, SVA003	Aungst Exhibit 46	Dup, E, H, R, 403, F
PTX-0018	2017-04-04	AMRIVAS0035367	AMRIVAS0035389	Vasopressin Injection, USP, End Product Test Procedure, STA-EXP-0119 revision 1	Hepner Exhibit 11	Dup, H, R, 403
PTX-0019	2017-04-04	AMRIVAS0035367	AMRIVAS0035389	Vasopressin Injection, USP, End Product Test Procedure, STA-EXP-0119 revision 1		Dup, H, R, 403
PTX-0020	2018-04-15	AMRIVAS0083622	AMRIVAS0083646	Commercial Supply Agreement between AMRI and Eagle Pharmaceuticals	Aungst Exhibit 8	Dup, H, R, 403, F
PTX-0021	2018-04-15	AMRIVAS0083622	AMRIVAS0083646	Commercial Supply Agreement between AMRI and Eagle Pharmaceuticals	Hepner Exhibit 18	Dup, H, R, 403, F
PTX-0022	2017-03-27	AMRIVAS0109709	AMRIVAS0109710	Vasopressin Injection, USP, AMRI Stability Data for SVA003.25I	Woltering Exhibit 40	R, 403
PTX-0023	2017-03-27	AMRIVAS0109832	AMRIVAS0109833	Vasopressin Injection, USP, AMRI Stability Data for SVA001.25I	Woltering Exhibit 42	R, 403
PTX-0024	2017-03-27	AMRIVAS0109834	AMRIVAS0109835	Vasopressin Injection, USP, AMRI Stability Data for SVA001.25U	Woltering Exhibit 43	R, 403
PTX-0025	2017-03-27	AMRIVAS0109840	AMRIVAS0109841	Vasopressin Injection, USP, AMRI Stability Data for SVA002.25I	Woltering Exhibit 44	R, 403
PTX-0026	2017-03-27	AMRIVAS0109842	AMRIVAS0109843	Vasopressin Injection, USP, AMRI Stability Data for SVA002.25U	Woltering Exhibit 45	R, 403
PTX-0027	2019-05-01	AMRIVAS0110033	AMRIVAS0110037	Vasopressin Injection, USP, AMRI Stability Data for SVA001.5I	Woltering Exhibit 33	I, Dup, R, 403
PTX-0028	2019-05-01	AMRIVAS0110033	AMRIVAS0110037	Vasopressin Injection, USP, AMRI Stability Data for SVA001.5I		I, Dup, R, 403
PTX-0029	2017-03-27	AMRIVAS0110038	AMRIVAS0110043	Vasopressin Injection, USP, AMRI Stability Data for SVA001.5U		I, Dup, R, 403
PTX-0030	2017-03-27	AMRIVAS0110038	AMRIVAS0110043	Vasopressin Injection, USP, AMRI Stability Data for SVA001.5U	Woltering Exhibit 34	I, Dup, R, 403
PTX-0031	2017-03-27	AMRIVAS0110044	AMRIVAS0110048	Vasopressin Injection, USP, AMRI Stability Data for SVA002.5I	Woltering Exhibit 35	Dup, R, 403
PTX-0032	2017-03-27	AMRIVAS0110044	AMRIVAS0110048	Vasopressin Injection, USP, AMRI Stability Data for SVA002.5I		Dup, R, 403
PTX-0033	2017-03-07	AMRIVAS0110049	AMRIVAS0110053	Vasopressin Injection, USP, AMRI Stability Data for SVA002.5U	Woltering Exhibit 36	Dup, R, 403
PTX-0034	2017-03-07	AMRIVAS0110049	AMRIVAS0110053	Vasopressin Injection, USP, AMRI Stability Data for SVA002.5U		Dup, R, 403
PTX-0035	2017-03-27	AMRIVAS0110054	AMRIVAS0110058	Vasopressin Injection, USP, AMRI Stability Data for SVA003.5I	Woltering Exhibit 37	Dup, R, 403
PTX-0036	2017-03-27	AMRIVAS0110054	AMRIVAS0110058	Vasopressin Injection, USP, AMRI Stability Data for SVA003.5I		Dup, R, 403
PTX-0037	2017-03-27	AMRIVAS0110059	AMRIVAS0110063	Vasopressin Injection, USP, AMRI Stability Data for SVA003.5I	Woltering Exhibit 38	E, Dup, R, 403
PTX-0038	2017-03-27	AMRIVAS0110059	AMRIVAS0110063	Vasopressin Injection, USP, AMRI Stability Data for SVA003.5I		E, Dup, R, 403
PTX-0039	2019-03-08	AMRIVAS0110443	AMRIVAS0110470	Vasopressin Injection, USP SVA004 Executed Batch Record, Compounding	Romito Exhibit 15	H, R, 403
PTX-0040	2019-03-14	AMRIVAS0110990	AMRIVAS0111046	Vasopressin Injection, USP SVA004 Executed Batch Record, Laboratory Tests	Romito Exhibit 16	H, R, 403
PTX-0041	2019-03-08	AMRIVAS0111192	AMRIVAS0111222	Vasopressin Injection, USP End Product Test Procedure, STA-EXP-0119 revision 4	Aungst Exhibit 27	Dup, H, R, 403
PTX-0042	2019-03-08	AMRIVAS0111192	AMRIVAS0111222	Vasopressin Injection, USP End Product Test Procedure, STA-EXP-0119 revision 4		Dup, H, R, 403
PTX-0043	2019-03-06	AMRIVAS0111402	AMRIVAS0111429	Vasopressin Injection, USP SVA005 Executed Batch Record, Compounding	Romito Exhibit 17	H, R, 403
PTX-0044	2019-04-08	AMRIVAS0111430	AMRIVAS0111457	Vasopressin Injection, USP SVA006 Executed Batch Record, Compounding	Romito Exhibit 19	H, R, 403
PTX-0045	2019-04-01	AMRIVAS0111954	AMRIVAS0111973	Vasopressin Injection, USP SVA005 Executed Batch Record, Laboratory Tests	Romito Exhibit 18	H, R, 403
PTX-0046	2019-04-07	AMRIVAS0111974	AMRIVAS0112035	Vasopressin Injection, USP SVA006 Executed Batch Record, Laboratory Tests	Romito Exhibit 20	H, R, 403
PTX-0047	2019-08-15	AMRIVAS0113567	AMRIVAS0113575	Deviation Report: ph Issues Observed during MBR Execution SVA007		H, R, 403, F, E
PTX-0048	2019-08-02	AMRIVAS0114108	AMRIVAS0114138	Vasopressin Injection, USP End Product Test Procedure STA-EXP-0119 revision 6	Woltering Exhibit 27	
PTX-0049	2019-08-09	AMRIVAS0114166	AMRIVAS0114189	Vasopressin Injection, USP, IN-Process Test Procedure	Woltering Exhibit 55	H, R, 403
PTX-0050	2019-08-08	AMRIVAS0114291	AMRIVAS0114391	Vasopressin Injection, SVA Master Batch Record, Version 9	Romito Exhibit 28	Dup, E, H, R, 403

EXHIBIT
23202

Par V. Eagle

Plaintiffs First Amended Exhibit List

PTX #	Date	Bates Begin	Bates End	Description	Depo. Exh No.	Objection(s)
PTX-0051	2017-02-20	AMRIVAS0114291	AMRIVAS0114391	Vasopressin Injection, USP, Master Batch Record, Document No. 10-869 version 9	Woltering Exhibit 47	Dup, E, H, R, 403
PTX-0052	2019-04-23	AMRIVAS0114545	AMRIVAS0114548	OOS Report - 24 Month SVA001.5U sample failed pH specification	Park Exhibit 24	Dup, H, R, 403
PTX-0053	2019-04-23	AMRIVAS0114545	AMRIVAS0114548	OOS Report - 24 Month SVA001.5U sample failed pH specification		Dup, H, R, 403
PTX-0054				Unused Number		Dup, E, H, R, 403
PTX-0055	2019-03-28	AMRIVAS0114545	AMRIVAS0114548	OOS Report - 24months, SVA001.5U Sample failed pH specification	Woltering Exhibit 39	Dup, H, R, 403
PTX-0056	2019-03-28	AMRIVAS0114545	AMRIVAS0114548	OOS Report- 24 month SVA001.5U sample failed pH specification	Aungst Exhibit 42	Dup, H, R, 403
PTX-0057	2018-03-28	AMRIVAS0114545	AMRIVAS0114548	OOS Report MN: 24 Month SVA 001.5U sample failed pH specification	Romito Exhibit 32	Dup, I, H, R, 403
PTX-0058	2017-03-05	AMRIVAS0114549		Certificate of Analysis Vasopressin SVA001	Aungst Exhibit 43	Dup, I, H, R, 403
PTX-0059	2017-03-05	AMRIVAS0114549		Certificate of Analysis Vasopressin SVA001		Dup, H, R, 403
PTX-0060	2019-03-27	AMRIVAS0114550	AMRIVAS0114553	Vasopressin Laboratory Investigation - Preliminary Investigation	Aungst Exhibit 44	Dup, R, 403
PTX-0061	2019-03-27	AMRIVAS0114550	AMRIVAS0114553	Vasopressin Laboratory Investigation - Preliminary Investigation		Dup, R, 403
PTX-0062	2013-06-07	AMRIVAS0114554	AMRIVAS0114567	SVA001/002/003 Data Record	Aungst Exhibit 45	Dup, R, 403
PTX-0063	2013-06-07	AMRIVAS0114554	AMRIVAS0114567	SVA001/002/003 Data Record		Dup, R, 403
PTX-0064	2017-03-27	AMRIVAS1019711	AMRIVAS1019712	Vasopressin Injection, USP, AMRI Stability Data for SVA003.25U	Woltering Exhibit 41	R, 403
PTX-0065	2017-02-20	EAGLESVA0002012	EAGLESVA0002037	Executed Batch Record for SVA001, Compounding	Woltering Exhibit 48	H, R, 403, 1006
PTX-0066	2017-02-20	EAGLESVA0002419	EAGLESVA0002444	Executed Batch Record for SVA002, Compounding	Woltering Exhibit 49	H, R, 403, 1006
PTX-0067	2019-08-02	EAGLEVAS00046178	EAGLEVAS00046210	Vasopressin Injection, USP End Product Test Procedure revision 6	Romito Exhibit 42	Dup
PTX-0068		EAGLEVAS00000001	EAGLEVAS0013663	Eagle ANDA No. 211538 Initial Production		IC, 1006, E, Dup, F, 403, R, H
PTX-0069	2018-03-19	EAGLEVAS00000001	EAGLEVAS00000005	Letter to Adrian Hepner referencing New Drug Application submitted under the FDA for Vasopressin Injection USP, 20 units/mL.	Woltering Exhibit 7	R,H, F, 403
PTX-0070	2018-01-25	EAGLEVAS00000013	EAGLEVAS00000018	Notice of Recertification of Vasopressin Injection USP, 20 units/1mL	Woltering Exhibit 11	Dup, H, R, F, 403
PTX-0071		EAGLEVAS00000013	EAGLEVAS00000018	Paragraph IV Acknowledgement and Receipt for Vasopressin Injection USP	Aungst Exhibit 12	Dup, H, R, F, 403
PTX-0072	2011-01-12	EAGLEVAS00000063	EAGLEVAS00000064	Module 1 1.12.11 Basis for Submission, NDA# 204485 Listed Drug: Vasostrict	Woltering Exhibit 3	Dup, E
PTX-0073		EAGLEVAS00000063	EAGLEVAS00000064	Module 1.12.11 Basis for Submission Vasostrict	Aungst Exhibit 3	Dup
PTX-0074	2012-01-12	EAGLEVAS00000076	EAGLEVAS00000077	Module 1 1.12.12 Comparison of Generic Drug RLD	Woltering Exhibit 4	Dup, E
PTX-0075		EAGLEVAS00000076	EAGLEVAS00000077	Vasopressin Injection USP, Module 1 1.12.12 Comparison of Generic Drug and RLD	Aungst Exhibit 4	Dup, E
PTX-0076	2018-01-01	EAGLEVAS00000298	EAGLEVAS00000303	Package Insert, Vasopressin Injection, USP		F, R, 403
PTX-0077	2018-01-01	EAGLEVAS00000304	EAGLEVAS00000304	Package Label, Vasopressin Injection, USP		F, R, 403
PTX-0078	2018-01-01	EAGLEVAS00000305	EAGLEVAS00000305	Container Label, Vasopressin Injection, USP		F, R, 403
PTX-0079	2018-01-01	EAGLEVAS00000306	EAGLEVAS00000308	Package Insert, Vasopressin Injection, USP		F, R, 403
PTX-0080	2018-01-01	EAGLEVAS00000309	EAGLEVAS00000310	Highlights of Prescribing Information: Vasopressin Injection, USP		F, R, 403
PTX-0081		EAGLEVAS00000334	EAGLEVAS00000335	Vasopressin Injection 20 Units per mL Carton		F, R, 403
PTX-0082	2018-01-25	EAGLEVAS00000372	EAGLEVAS00000380	Letter dated 1/25/2018 submitting Application for a New Drug of Vasopressin Injection, USP 20 units per mL.	Woltering Exhibit 5	Dup
PTX-0083	2018-01-25	EAGLEVAS00000372	EAGLEVAS00000380	Letter from Eagle submitting an original ANDA for Vasopressin Injection USP 20 units per mL	Hepner Exhibit 4	Dup, I, E
PTX-0084		EAGLEVAS00000409	EAGLEVAS00000410	Vasopressin Injection USP, Module 2, 2.3.P.1 Description and Composition of the Drug Product		
PTX-0085		EAGLEVAS00000458	EAGLEVAS00000463	Module 2 3.2.P1 Description and Composition of the Drug Product Vasopressin Injection, USP		Dup, E
PTX-0086		EAGLEVAS00000458	EAGLEVAS00000463	Module 2 3.2.P1 Description and Composition of the Drug Product Vasopressin Injection, USP	Woltering Exhibit 12	Dup, E
PTX-0087		EAGLEVAS00000458	EAGLEVAS00000463	Module 3 3.2.P.1 Description and Composition of the Drug Product - Vasostrict, Vasopressin Injection, USP	Aungst Exhibit 13	Dup
PTX-0088		EAGLEVAS00000458	EAGLEVAS00000463	Vasopressin Injection, USP Module 3.2.P.1 Description and Composition of the Drug Product	Romito Exhibit 34	Dup
PTX-0089		EAGLEVAS00000650	EAGLEVAS00000660	Vasopressin Injection USP, Module 3, 3.2.P.2 Pharmaceutical Development		R, 403
PTX-0090		EAGLEVAS00000670	EAGLEVAS00000710	Module 3 3.2.P2 Pharmaceutical Development of the Drug Product Vasopressin Injection, USP	Woltering Exhibit 14	Dup, R, 403
PTX-0091		EAGLEVAS00000670	EAGLEVAS00000710	Module 3 3.2.P2 Pharmaceutical Development of the Drug Product Vasopressin Injection, USP		Dup, R, 403

EXHIBIT
23703

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Plaintiffs First Amended Exhibit List

PTX #	Date	Bates Begin	Bates End	Description	Depo. Exh No.	Objection(s)
PTX-0092	2017-09-18	EAGLEVAS0000863	EAGLEVAS0000874	Determination of Assay and Related Substances of Vasopressin Injection	Woltering Exhibit 25	Dup, R, 403
PTX-0093	2017-09-18	EAGLEVAS0000863	EAGLEVAS0000874	Determination of Assay and Related Substances of Vasopressin Injection	Aungst Exhibit 24	Dup, R, 403
PTX-0094		EAGLEVAS0001328	EAGLEVAS0001329	Module 3 3.2.P.5.1 Vasopressin Specifications Control of the Drug Product, Original Submission	Romito Exhibit 36	Dup, R, 403
PTX-0095		EAGLEVAS0001328	EAGLEVAS0001329	Module 3.2.P.5.1 Specifications for Vasopressin Injection USP	Woltering Exhibit 16	Dup, R, 403
PTX-0096		EAGLEVAS0001328	EAGLEVAS0001329	Module 3.2.P.5.1 Specifications for Vasopressin Injection USP		Dup, R, 403
PTX-0097		EAGLEVAS0001328	EAGLEVAS0001329	Module 3.2.P.5.2 Specifications Vasopressin Injection USP, Original ANDA Submission		Dup, E, R, 403
PTX-0098		EAGLEVAS0001328	EAGLEVAS0001329	Module 3.2.P.5.2 Specifications Vasopressin Injection USP, Original ANDA Submission	Aungst Exhibit 20	Dup, E, R, 403
PTX-0099	2018-01-15	EAGLEVAS0001330	EAGLEVAS0001330	Module 3, 3.2.P.5.2 Analytical Procedures		R, F, 403
PTX-0100	2018-01-15	EAGLEVAS0001331	EAGLEVAS0001348	Acceptance Criteria for Vasopressin API, USP, Document No. STA-ATX-0126		R, 403
PTX-0101	2018-01-17	EAGLEVAS0001349	EAGLEVAS0001380	Vasopressin Injection, USP End Product Test Procedure revision 3	Romito Exhibit 46	R, 403
PTX-0102	2018-01-17	EAGLEVAS0001349	EAGLEVAS0001380	Vasopressin Injection, USP End Product Test Procedure STA-EPX-0119 revision 3	Woltering Exhibit 26	Dup, R, 403
PTX-0103	2018-01-17	EAGLEVAS0001349	EAGLEVAS0001380	Vasopressin Injection, USP End Product Test Procedure STA-EPX-0119 revision 3		Dup, R, 403
PTX-0104	2018-01-17	EAGLEVAS0001349	EAGLEVAS0001380	Vasopressin Injection, USP End Product Test Procedure, STA-EPX-0119 revision 3	Aungst Exhibit 26	Dup, R, 403
PTX-0105	2016-11-23	EAGLEVAS0001435	EAGLEVAS0001466	Method Validation Report for Assay and Related Substances in Vasopressin Injection	Aungst Exhibit 25	R, 403
PTX-0106	2017-03-03	EAGLEVAS0001743	EAGLEVAS0001744	Certificate of Analysis: Vasopressin Injection, USP		E
PTX-0107		EAGLEVAS0001749	EAGLEVAS0001754	Module 2 3.2.P.5.5 Characterization of Impurities: Vasopressin Injection	Woltering Exhibit 22	Dup, R, 403
PTX-0108		EAGLEVAS0001749	EAGLEVAS0001754	Vasopressin Injection USP, Module 3 3.2.P.5.1 Characterization of Impurities Original Submission	Romito Exhibit 47	Dup, R, 403
PTX-0109		EAGLEVAS0001749	EAGLEVAS0001754	Vasopressin Injection USP, Module 3 3.2.P.5.1 Characterization of Impurities Original Submission		Dup, E, R, 403
PTX-0110		EAGLEVAS0001749	EAGLEVAS0001754	Module 3.2.P.5.5 Characterization of Impurities	Aungst Exhibit 35	R, 403
PTX-0111	2018-01-13	EAGLEVAS0001867	EAGLEVAS0001872	Post Approval Stability Commitment and Protocol for Vasopressin Injection (0.0377 MG/ML) USP	Woltering Exhibit 18	R, 403
PTX-0112	2017-03-03	EAGLEVAS0001873	EAGLEVAS0001904	Module 3 3.2.P.8.3 Stability Data: Vasopressin Injection USP	Hepner Exhibit 10	Dup, R, 403
PTX-0113	2017-03-03	EAGLEVAS0001873	EAGLEVAS0001904	Module 3 3.2.P.8.3 Stability Data: Vasopressin Injection USP		Dup, R, 403
PTX-0114		EAGLEVAS0001905	EAGLEVAS0001920	Module 3 3.2.P.8.1 Stability Summary and Conclusion for Vasopressin Injection, USP	Woltering Exhibit 17	R, 403
PTX-0115	2017-03-03	EAGLEVAS0001921	EAGLEVAS0002327	SVA001 - Executed Batch Record	Aungst Exhibit 17	Dup, H, R, 403, 1006, E
PTX-0116	2017-03-03	EAGLEVAS0001921	EAGLEVAS0002327	SVA001 - Executed Batch Record		Dup, H, R, 403, 1006, E
PTX-0117		EAGLEVAS0002012	EAGLEVAS0002037	Vasopressin Injection, USP SVA001 Executed Batch Record, Compounding	Romito Exhibit 9	H, R, 403
PTX-0118	2017-03-24	EAGLEVAS0002276	EAGLEVAS0002319	Vasopressin Injection, USP SVA001 Executed Batch Record, Laboratory Tests	Romito Exhibit 10	H, R, 403
PTX-0119	2017-03-05	EAGLEVAS0002277		Certificate of Analysis : Vasopressin SVA001	Kirsch 21	H, R, 403
PTX-0120	2017-03-07	EAGLEVAS0002328	EAGLEVAS0002682	SVA002 - Executed Batch Record	Aungst Exhibit 18	R, 403, 1006, E, H
PTX-0121	2017-02-17	EAGLEVAS0002419	EAGLEVAS0002444	Vasopressin Injection, USP SVA002 Executed Batch Record, Compounding	Romito Exhibit 11	H, R, 403
PTX-0122	2017-03-07	EAGLEVAS0002640	EAGLEVAS0002677	Vasopressin Injection, USP SVA002 Executed Batch Record, Laboratory Tests	Romito Exhibit 12	H, R, 403
PTX-0123	2017-03-30	EAGLEVAS0002683	EAGLEVAS0003071	SVA003 - Executed Batch Record	Aungst Exhibit 19	1006, E, H, R, 403
PTX-0124	2017-02-17	EAGLEVAS0002778	EAGLEVAS0002804	Vasopressin Injection, USP SVA003 Executed Batch Record, Compounding	Romito Exhibit 13	Dup, H, R, 403
PTX-0125	2017-02-20	EAGLEVAS0002778	EAGLEVAS0002804	Executed Batch Record for SVA003, Compounding	Woltering Exhibit 50	Dup, H, R, 403
PTX-0126	2017-03-14	EAGLEVAS0003035	EAGLEVAS0003071	Vasopressin Injection, USP SVA003 Executed Batch Record, Laboratory Tests	Romito Exhibit 14	H, R, 403
PTX-0127	2018-03-23	EAGLEVAS0010623	EAGLEVAS0010635	Amendment: Request for Reconsideration of refuse-to- receive decision re: Vasopressin Injection, USP, 20 units per mL	Woltering Exhibit 9	R, 403
PTX-0128	2018-03-23	EAGLEVAS0010689	EAGLEVAS0010690	Vasopressin Injection, USP, 20 Units per mL Response to Refuse-to-Receive Letter	Woltering Exhibit 10	R, 403
PTX-0129		EAGLEVAS0010723	EAGLEVAS0010840	Module 2 Supplement: Question-based Review for Drug Product Vasopressin Injection, USP	Woltering Exhibit 28	Dup
PTX-0130		EAGLEVAS0010845	EAGLEVAS0010962	Vasopressin Injection USP, Module 2 Supplement: Question-based Review for Drug Product		Dup
PTX-0131		EAGLEVAS0011160	EAGLEVAS0011160	Vasopressin Injection USP, Module 3.2.P.3.2 Batch Formula		
PTX-0132		EAGLEVAS0011590	EAGLEVAS0011615	Module 2 3.2.P.8.3 Stability Data for Vasopressin Injection, USP	Woltering Exhibit 19	Dup, R, 403
PTX-0133		EAGLEVAS0011590	EAGLEVAS0011615	Module 2 3.2.P.8.3 Stability Data for Vasopressin Injection, USP		Dup, R, 403

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23204

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Plaintiffs First Amended Exhibit List

PTX #	Date	Bates Begin	Bates End	Description	Depo. Exh No.	Objection(s)
PTX-0134		EAGLEVAS0012145	EAGLEVAS0012185	Module 3 3.2.P2 Pharmaceutical Development of the Drug Product Vasopressin Injection, USP	Woltering Exhibit 13	Dup, R, 403
PTX-0135		EAGLEVAS0012145	EAGLEVAS0012185	Module 3 3.2.P.2 Pharmaceutical Development - Vasopressin Injection, USP	Aungst Exhibit 14	Dup, R, 403
PTX-0136		EAGLEVAS0012145	EAGLEVAS0012185	Module 3 3.2.P.2 Pharmaceutical Development - Vasopressin Injection, USP		Dup, R, 403
PTX-0137		EAGLEVAS0012814	EAGLEVAS0012814	Vasopressin Carton label		R, F, 403
PTX-0138	2018-05-01	EAGLEVAS0012937	EAGLEVAS0012938	Vasopressin Injection, Draft Product Insert		R, 403
PTX-0139	2018-10-11	EAGLEVAS0013355	EAGLEVAS0013380	Response to Discipline Letter: Vasopressin Injection, USP		Dup, R, 403
PTX-0140	2018-10-11	EAGLEVAS0013355	EAGLEVAS0013380	Response to Discipline Letter: Vasopressin Injection, USP	Woltering Exhibit 29	Dup, R, 403
PTX-0141	2018-10-15	EAGLEVAS0013381	EAGLEVAS0013407	Patent Verification Statement: Vasopressin Injection, USP	Woltering Exhibit 30	R, 403
PTX-0142	2018-05-25	EAGLEVAS0013502	EAGLEVAS0013507	Stability Protocol for: Vasopressin Injection (0.0377mg/mL)	Woltering Exhibit 21	Dup, R, 403
PTX-0143	2018-05-25	EAGLEVAS0013502	EAGLEVAS0013507	Stability Protocol for: Vasopressin Injection (0.0377mg/mL)		Dup, R, 403
PTX-0144		EAGLEVAS0014005		PPC Label Vasopressin Injection USP	Chyall Exhibit 14	
PTX-0145	2012-09-25	EAGLEVAS0014051	EAGLEVAS0014364	Biopharmaceutics Review NDA 204485		Dup, H, R, F, 403, 1006, E
PTX-0146	2012-09-26	EAGLEVAS0014051	EAGLEVAS0014355	Biopharmaceutics Review: Vasopressin Injection, USP	Park Exhibit 15	Dup, H, R, F, 403, IN, 1006
PTX-0147	2012-09-26	EAGLEVAS0014351	EAGLEVAS0014364	Biopharmaceutics Review: Vasopressin Injection, USP	Kirsch 26	Dup, H, R, F, 403, 1006
PTX-0148	2012-09-26	EAGLEVAS0014351	EAGLEVAS0014364	Vasopressin Injection Biopharmaceutics Review	English Exhibit 15	Dup, H, R, F, 403, 1006
PTX-0149	2019-01-18	EAGLEVAS0032660	EAGLEVAS0032671	Eagle ANDA No. 211538 FDA Complete Response Letter		Dup, R, 403
PTX-0150	2019-01-18	EAGLEVAS0032660	EAGLEVAS0032671	Letter to response of denying ANDA for Vasopressin, Injection, USP	Woltering Exhibit 31	Dup, E, R, 403
PTX-0151				Unused Number		Dup, E
PTX-0152		EAGLEVAS0036325	EAGLEVAS0036328	Vasopressin Highlights of Prescribing Information Sept. 2014	Park Exhibit 9	MISSING, IN
PTX-0153	2015-06-01	EAGLEVAS0038897	EAGLEVAS0038905	Adamsons 1958 - The Stability of Natural and Synthetic Neurophysial Hormones in Vitro		H, R, F, 403
PTX-0154		EAGLEVAS0043551	EAGLEVAS0043551	Eagle ANDA No. 211538 Sequence 19 Native Production		H, R, F, IN, 403, 1006, IC
PTX-0155		EAGLEVAS0043552	EAGLEVAS0051562	Eagle ANDA No. 211538 Sequence 19 Production		H, R, F, IN, 403, 1006, IC
PTX-0156		EAGLEVAS0043565		Vasopressin Vial Carton (2019)	Hepner Exhibit 7	I, H, R, F, 403
PTX-0157		EAGLEVAS0043566	EAGLEVAS0043568	Ex B - Vasopressin Injection USP, Highlights of Prescribing Information		Dup
PTX-0158		EAGLEVAS0043566	EAGLEVAS0043568	September 2019 Package Insert for Vasopressin Injection, USP.		Dup
PTX-0159		EAGLEVAS0043566	EAGLEVAS0043568	September 2019 Package Insert for Vasopressin Injection, USP.	Cross Exhibit 5	Dup
PTX-0160	2019-9-xx	EAGLEVAS0043566	EAGLEVAS0043568	September 2019 Package Insert for Vasopressin Injection, USP.	Hepner Exhibit 5	Dup
PTX-0161		EAGLEVAS0043566	EAGLEVAS0043568	September 2019 Package Insert for Vasopressin Injection, USP.	Romito Exhibit 5	Dup
PTX-0162		EAGLEVAS0043566	EAGLEVAS0043568	September 2019 Package Insert for Vasopressin Injection, USP.	Park Exhibit 21	Dup
PTX-0163		EAGLEVAS0043596	EAGLEVAS0043596	Vasopressin Injection USP Carton	Hepner Exhibit 6	I, R, F, 403, Dup
PTX-0164		EAGLEVAS0043596	EAGLEVAS0043596	Vasopressin Injection USP Carton		R, F, 403, Dup
PTX-0165		EAGLEVAS0043596		Vasopressin Injection USP Carton	Romito Exhibit 7	I, R, F, 403, Dup
PTX-0166		EAGLEVAS0043597		Vasopressin Injection, USP Vial Label	Hepner Exhibit 8	R, F, 403, Dup
PTX-0167		EAGLEVAS0043597		Vasopressin Injection, USP Vial Label		R, F, 403, Dup
PTX-0168	2019-09-11	EAGLEVAS0043614	EAGLEVAS0043663	Resubmission - Major Complete Response Amendment Dug Substance/Process/Microbiology	Kirsch 20	Dup, E, H, R, F, 403
PTX-0169	2019-09-11	EAGLEVAS0043614	EAGLEVAS0043663	Resubmission - Major Complete Response Amendment Dug Substance/Process/Microbiology	Hepner Exhibit 14	Dup, E, H, R, F, 403
PTX-0170	2019-09-11	EAGLEVAS0043614	EAGLEVAS0043663	Resubmission - Major Complete Response Amendment Dug Substance/Process/Microbiology		Dup, E, H, R, F, 403
PTX-0171		EAGLEVAS0043670	EAGLEVAS0043790	Module 2 Supplement: Question-based Review for Drug Product Vasopressin Injection, USP	Hepner Exhibit 9	Dup
PTX-0172		EAGLEVAS0043670	EAGLEVAS0043790	Module 2 Supplement: Question-based Review for Drug Product Vasopressin Injection, USP		Dup

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23205

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Plaintiffs First Amended Exhibit List

PTX #	Date	Bates Begin	Bates End	Description	Depo. Exh No.	Objection(s)
PTX-0173		EAGLEVAS0045423		Vasopressin Module 3.2.P.3 Manufacture Batch Formula	Romito Exhibit 35	Dup
PTX-0174		EAGLEVAS0045423		Vasopressin Module 3.2.P.3 Manufacture Batch Formula		Dup
PTX-0175		EAGLEVAS0045429	EAGLEVAS0045443	Module 3 3.2.P.3.4 Controls of Critical Steps and Intermediates	Romito Exhibit 29	Dup
PTX-0176		EAGLEVAS0045429	EAGLEVAS0045443	Module 3 3.2.P.3.4 Controls of Critical Steps and Intermediates	Aungst Exhibit 29	Dup
PTX-0177		EAGLEVAS0045476	EAGLEVAS0045508	Module 3.2.P.3.3 Description of Manufacturing Process and Process Controls - Vasopressin Injection, USP	Aungst Exhibit 15	Dup
PTX-0178		EAGLEVAS0045476	EAGLEVAS0045508	Vasopressin Module 3 3.2.P.3.3 Description of Manufacturing Process and Process Controls	Romito Exhibit 31	Dup, E
PTX-0179		EAGLEVAS0045476	EAGLEVAS0045508	Vasopressin Module 3 3.2.P.3.3 Description of Manufacturing Process and Process Controls		Dup, E
PTX-0180	2019-08-29	EAGLEVAS0045509	EAGLEVAS0045605	Vasopressin Injection, SVA Master Batch Record, Proposed Commercial	Romito Exhibit 27	Dup, R, 403
PTX-0181	2019-08-29	EAGLEVAS0045509	EAGLEVAS0045605	Vasopressin Injection, SVA Master Batch Record, Proposed Commercial		Dup, R, 403
PTX-0182	2019-08-09	EAGLEVAS0045607	EAGLEVAS0045632	Vasopressin Injection, USP In-Process Test Procedure, STA-IPX-0153 revision 4	Aungst Exhibit 32	
PTX-0183		EAGLEVAS0045725	EAGLEVAS0045847	Vasopressin Injection, USP V1926 Summary Report		
PTX-0184		EAGLEVAS0046173	EAGLEVAS0046175	Module 3 3.2.P. Control of Drug Product : Drug Product Release and Stability Specification	Hepner Exhibit 17	Dup, E
PTX-0185		EAGLEVAS0046173	EAGLEVAS0046175	Module 3 3.2.P.5 Specifications: Control of Drug Product	Park Exhibit 20	Dup, E
PTX-0186		EAGLEVAS0046173	EAGLEVAS0046175	Module 3 3.2.P.5 Specifications: Control of Drug Product		Dup, E
PTX-0187		EAGLEVAS0046173	EAGLEVAS0046175	Module 3 3.2.P.5.1 Vasopressin Specifications Control of the Drug Product, Sequence 19 Submission	Romito Exhibit 37	Dup, E
PTX-0188		EAGLEVAS0046173	EAGLEVAS0046175	Module 3.2.P.5.2 Specifications Vasopressin Injection USP, Sequence 19 Submission	Aungst Exhibit 21	Dup, E
PTX-0189		EAGLEVAS0046176	EAGLEVAS0046177	Module 3 3.2.P.5 f Analytical Procedures Vasopressin Injection, USP	Aungst Exhibit 23	Dup, E
PTX-0190		EAGLEVAS0046176	EAGLEVAS0046177	Module 3 3.2.P.5 Vasopressin Analytical Procedures	Romito Exhibit 38	Dup, E
PTX-0191	2019-08-02	EAGLEVAS0046178	EAGLEVAS0046210	Vasopressin Injection, USP End Product Test Procedure, STA-EPX-0119 revision 6		Dup
PTX-0192	2019-08-02	EAGLEVAS0046178	EAGLEVAS0046210	Vasopressin Injection, USP End Product Test Procedure, STA-EPX-0119 revision 6	Aungst Exhibit 28	Dup
PTX-0193		EAGLEVAS0046416	EAGLEVAS0046418	Module 3.2.P.5.3 Validation of Analytical Procedures	Aungst Exhibit 22	R, 403
PTX-0194		EAGLEVAS0046449	EAGLEVAS0046457	Vasopressin Injection USP, Module 3 3.2.P.5 Characterization of Impurities	Hepner Exhibit 16	Dup, E, R, 403
PTX-0195		EAGLEVAS0046449	EAGLEVAS0046457	Vasopressin Injection USP, Module 3 3.2.P.5 Characterization of Impurities		Dup, E, R, 403
PTX-0196		EAGLEVAS0046449	EAGLEVAS0046457	Vasopressin Injection USP, Module 3 3.2.P.5.1 Characterization of Impurities Sequence 19 Submission	Romito Exhibit 48	Dup, E, R, 403
PTX-0197		EAGLEVAS0046449	EAGLEVAS0046457	Module 3.2.P.5.5 Characterization of Impurities	Aungst Exhibit 36	Dup, E, R, 403
PTX-0198	2019-08-20	EAGLEVAS0046633	EAGLEVAS0046742	ETR132: Assessment of the Trisulfide Vasopressin Impurity in Vasopressin Injection USP Statistical Evaluation and Specification Recommendation	Romito Exhibit 39	Dup, E, R, 403, F
PTX-0199	2019-08-20	EAGLEVAS0046633	EAGLEVAS0046742	ETR132: Assessment of the Trisulfide Vasopressin Impurity in Vasopressin Injection USP Statistical Evaluation and Specification Recommendation		Dup, E, R, 403, F
PTX-0200		EAGLEVAS0046633	EAGLEVAS0046742	Stability Results for SVA001, SVA002, SVA003	Aungst Exhibit 47	Dup, E, R, 403, F
PTX-0201		EAGLEVAS0047249		3.2.P.8.2 Post-Approval Stability Protocol and Stability Commitment	Park Exhibit 25	
PTX-0202		EAGLEVAS0047270	EAGLEVAS0047273	Module 3.2.P.8 Stability Data	Aungst Exhibit 37	Dup, E
PTX-0203		EAGLEVAS0047270	EAGLEVAS0047273	Vasopressin Injection, USP 3.2.P.8.3 Stability Data		Dup
PTX-0204	2017-03-03	EAGLEVAS0047274	EAGLEVAS0047277	Vasopressin Injection, USP 0.377 mg/ML, 2017 Registration Batch, Batch SVA001 Long Term Stability Data	Aungst Exhibit 38	Dup, E
PTX-0205	2017-03-03	EAGLEVAS0047274	EAGLEVAS0047277	Vasopressin Injection, USP 2017 Registration Batch SVA001 stability data	Romito Exhibit 43	Dup, E, H, R, 403
PTX-0206	2017-03-27	EAGLEVAS0047274	EAGLEVAS0047324	Vasopressin Injection, USP Compilation of Stability Data for SVA001-SVA006	Hepner Exhibit 12	Dup, E, IC, H, R, 403
PTX-0207		EAGLEVAS0047274	EAGLEVAS0047277	Vasopressin Injection, USP Registration Batch SVA001 stability data	Kirsch 8	Dup, E, H, R, 403
PTX-0208		EAGLEVAS0047274	EAGLEVAS0047277	Vasopressin Injection, USP Registration Batch SVA001 stability data		Dup, E
PTX-0209	2017-03-07	EAGLEVAS0047284	EAGLEVAS0047287	Vasopressin Injection, USP 0.377 mg/ML, 2017 Registration Batch, Batch SVA002 Long Term Stability Data	Aungst Exhibit 39	Dup, E, H, R, 403
PTX-0210	2017-03-07	EAGLEVAS0047284	EAGLEVAS0047287	Vasopressin Injection, USP 2017 Registration Batch SVA002 stability data	Romito Exhibit 44	Dup, E, H, R, 403
PTX-0211	2017-03-10	EAGLEVAS0047294	EAGLEVAS0047297	Vasopressin Injection, USP 0.377 mg/ML, 2017 Registration Batch, Batch SVA003 Long Term Stability Data	Aungst Exhibit 41	Dup, E, H, R, 403
PTX-0212	2017-03-10	EAGLEVAS0047294	EAGLEVAS0047297	Vasopressin Injection, USP 2017 Registration Batch SVA003 stability data	Romito Exhibit 45	Dup, E, H, R, 403
PTX-0213	2017-03-10	EAGLEVAS0047301	EAGLEVAS0047303	Vasopressin Injection, USP 2017 Registration Batch SVA003A stability data	Aungst Exhibit 40	Dup, E, H, R, 403

EXHIBIT 2
23206

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Plaintiffs First Amended Exhibit List

PTX #	Date	Bates Begin	Bates End	Description	Depo. Exh No.	Objection(s)
PTX-0214		EAGLEVAS0047328	EAGLEVAS0047355	Module 3 3.2.P.8 Stability Summary and Conclusion	Romito Exhibit 30	Dup, E, H, R, 403
PTX-0215		EAGLEVAS0047328	EAGLEVAS0047355	Module 3 3.2.P.8 Stability Summary and Conclusion	Hepner Exhibit 13	Dup, E, H, R, 403
PTX-0216		EAGLEVAS0047328	EAGLEVAS0047355	Module 3 3.3.P.8 Stability Summary and Conclusion	Park Exhibit 23	Dup, E, H, R, 403
PTX-0217		EAGLEVAS0047328	EAGLEVAS0047355	Module 3.2.P.8 Stability Summary and Conclusion	Aungst Exhibit 30	Dup, E, H, R, 403
PTX-0218		EAGLEVAS0047328	EAGLEVAS0047355	Vasopressin Injection, USP, Module 3, 3.2.P.8 Stability		Dup, E, H, R, 403
PTX-0219	2019-08-22	EAGLEVAS0047362	EAGLEVAS0048071	SVA007 - Executed Batch Record	Aungst Exhibit 31	Dup, E, 1006, H, R, 403
PTX-0220	2019-08-22	EAGLEVAS0047362	EAGLEVAS0048071	SVA007 - Executed Batch Record		Dup, E, 1006, H, R, 403
PTX-0221	2019-07-03	EAGLEVAS0047572	EAGLEVAS0047613	Vasopressin Injection, USP SVA007 Executed Batch Record, Compounding	Romito Exhibit 21	Dup, I, E, H, R, 403
PTX-0222	2019-07-12	EAGLEVAS0047964	EAGLEVAS0048013	Vasopressin Injection, USP SVA007 Executed Batch Record, Laboratory Tests	Romito Exhibit 22	Dup, H, R, 403
PTX-0223	2019-08-16	EAGLEVAS0048072	EAGLEVAS0048666	SVA0008 - Vasopressin Injection, USP 0.377, Batch/Release Rejection Form		Dup, E, H, R, 403, 1006
PTX-0224	2019-07-12	EAGLEVAS0048202	EAGLEVAS0048253	Vasopressin Injection, USP SVA008 Executed Batch Record, Compounding	Romito Exhibit 23	Dup, E, H, R, 403
PTX-0225	2019-07-17	EAGLEVAS0048569	EAGLEVAS0048632	Vasopressin Injection, USP SVA008 Executed Batch Record, Laboratory Tests	Romito Exhibit 24	Dup, H, R, 403
PTX-0226	2019-07-26	EAGLEVAS0048572	EAGLEVAS0048573	Certificate of Analysis Vasopressin Injection, SVA 008	Aungst Exhibit 33	Dup, I, H, R, 403
PTX-0227	2019-08-29	EAGLEVAS0048667	EAGLEVAS0049378	SVA0009 - Vasopressin Injection USP, 0.0377, Batch/Release Rejection Form		Dup, 1006, H, R, 403
PTX-0228	2019-08-08	EAGLEVAS0048961	EAGLEVAS0049010	Vasopressin Injection, USP SVA009 Executed Batch Record, Compounding	Romito Exhibit 25	Dup, H, R, 403
PTX-0229	2019-07-18	EAGLEVAS0049284	EAGLEVAS0049348	Vasopressin Injection, USP SVA009 Executed Batch Record, Laboratory Tests	Romito Exhibit 26	Dup, H, R, 403
PTX-0230	2019-08-22	EAGLEVAS0049345	EAGLEVAS0049346	Certificate of Analysis Vasopressin Injection, SVA 009	Aungst Exhibit 34	Dup, H, R, 403
PTX-0231		EAGLEVAS0052180	EAGLEVAS0052184	AHFS 2011		E, I
PTX-0232		EAGLEVAS0058064	EAGLEVAS0058337	Yoshioka, S. and Stella, V. Stability of Drugs and Dosage Forms. Kluwer Academic Publishers 2012		1006
PTX-0233	2017-06-27	PAR-VASO_0000034	PAR-VASO_0000113	United States Patent No: US 9,687,526 B2	Chyall Exhibit 2	Dup, I
PTX-0234	2017-08-29	PAR-VASO_0000114	PAR-VASO_0000197	United States Patent No: US 9,744,209 B2	Chyall Exhibit 3	Dup, I
PTX-0235	2017-09-05	PAR-VASO_0000232	PAR-VASO_0000314	Certified copy of United States Patent 9,750,785: Vasopressin Formulations for Use in Treatment of Hypotension	Chyall Exhibit 4	Dup, I
PTX-0236	2015-05-20	PAR-VASO_0000977	PAR-VASO_00001013	United States Patent and Trademark Filing Application	Chyall Exhibit 12	Dup, E
PTX-0237	2016-01-22	PAR-VASO_0002304	PAR-VASO_0002317	Declaration under 37 CFR by Inventor Sunil Vandse	Chyall Exhibit 6	Dup, E
PTX-0238	2016-03-31	PAR-VASO_0002580	PAR-VASO_0002590	Declaration under 37 CFR by Vinayagam Kannan	Chyall Exhibit 7	Dup, E, I
PTX-0239	2015-08-11	PAR-VASO_0004903	PAR-VASO_0004910	Declaration under 37 CFR by Inventor Sunil Vandse	Chyall Exhibit 5	Dup, E, I
PTX-0240	2015-05-20	PAR-VASO_0008388	PAR-VASO_0008390	Declaration under 37 CFR by Vinayagam Kannan	Chyall Exhibit 10	Dup, E
PTX-0241	2015-05-20	PAR-VASO_0008804	PAR-VASO_0008824	Declaration under 37 CFR by Vinayagam Kannan	Chyall Exhibit 8	Dup, E
PTX-0242	2014-06-03	PAR-VASO_0014805	PAR-VASO_0014809	Letter - General Advice on Content of Labeling for Vasostrict	English Exhibit 14	I
PTX-0243	2012-09-25	PAR-VASO_0015573	PAR-VASO_0015586	FDA NDA Approval Letter	Chyall Exhibit 13	Dup, E
PTX-0244	2012-09-25	PAR-VASO_0015573	PAR-VASO_0015586	Letter acknowledging receipt of amendments for Vasostrict	English Exhibit 7	Dup, E
PTX-0245	2017-06-05	PAR-VASO_0024408	PAR-VASO_0024421	Tabulated Stability Data through 23 Month Interval		H, A, R, 403, F
PTX-0246	2009-03-16	PAR-VASO_0025902	PAR-VASO_0025949	JHP Research Report 703-00159 Analytical Method Validation Report for the Determination of Vasopressin and Impurities in Pitressin Gradient HPLC		H, A, R, 403, F
PTX-0247	2014-10-21	PAR-VASO_0028307	PAR-VASO_0028352	Pharmaceutical Development Technical Report - Document Approval (FRD-14-001R)	Park Exhibit 27	H, A, R, F, 403
PTX-0248	2014-10-21	PAR-VASO_0028307	PAR-VASO_0028352	Vasostrict (Vasopressin injection, USP) Justification of Time Out of Refrigeration	Kannan Exhibit 16	Dup, H
PTX-0249	2014-08-26	PAR-VASO_0029501	PAR-VASO_0029502	Chain email from P. Dardaine to M. Kenney re SA Rochester Slides 8/29/14 Updated needed (redacted)		H, A, R, F, 403
PTX-0250		PAR-VASO_0030050	PAR-VASO_0030052	2014-05-28 Meeting Minutes		H, A, R, F, 403
PTX-0251	2015-10	PAR-VASO_0030399	PAR-VASO_0030458	PAR Vasostrict, 20 Unites/mL, pH 3.8 Acetate Buffer, Single Dose (Preservative Free) (Stock # 2002501) Product Development Technical Report FRD-15-012		H, A, Dup, R, F, 403
PTX-0252		PAR-VASO_0030563	PAR-VASO_0030582	Product Development Stability Summary, Room Temperature Evaluation for Vasostrict pH 3.8 Acetate Buffer, Single Dose (Stock # 2002501)		H, A, R, F, 403
PTX-0253	2016-02-17	PAR-VASO_0030979	PAR-VASO_00310015	Vasostrict, 20 units per ml Product Development Technical Report	Boesch Exhibit 13	H, A, Dup, R, F, 403
PTX-0254	2013-05-09	PAR-VASO_0031687	PAR-VASO_0031708	Product Development Procedure Validation Report		H, A
PTX-0255	2017-06-05	PAR-VASO_0042538	PAR-VASO_0042551	Vaso 1mL stk 2002501_23M data for OOR studies_07Jun17.pdf		Dup, H, A, R, 403, F

EXHIBIT 7
23207

Par V. Eagle

Plaintiffs First Amended Exhibit List

PTX #	Date	Bates Begin	Bates End	Description	Depo. Exh No.	Objection(s)
PTX-0256	2016-09-07	PAR-VASO_0046745		Vasostrict, 20 Units.ML Stability Request/Initiation	Chyall Exhibit 20	H, A, R, 403, F
PTX-0257	2017-03-03	EAGLEVAS0047274	EAGLEVAS0047277	Vasopressin Injection, USP Registration Batch SVA001, Stability Data	Park Exhibit 22	H, Dup, E, R, 403
PTX-0258	2015-01-27	PAR-VASO_0059897	PAR-VASO_0059949	Par R&D Lab Notebook of Vinayagam Kannan No. 44 Project Vasostrict		H, R, 403
PTX-0259	2014-06-01	PAR-VASO_0059950	PAR-VASO_0060041	Par R&D Lab Notebook of Kenney No. 71 Project Pitressin Formulation	Kenney Exhibit 23	H, Dup, R, 403
PTX-0260		PAR-VASO_0059950	PAR-VASO_0060041	Par R&D Lab Notebook of Kenney No. 71 Project Pitressin Formulation	Chyall Exhibit 19	H, Dup, R, 403
PTX-0261		PAR-VASO_0060083	PAR-VASO_0060106	3 month-Interim Stability Summary Vasostrict pH 3.8 Acetate Buffer, Multiple Dose (Stock # 2002525)		H, A, DUP, R,, F, 403
PTX-0262		PAR-VASO_0060127	PAR-VASO_0060163	Product Development Technical Report FRD-16-001		H, A, DUP, R, F, 403
PTX-0263		PAR-VASO_0060713	PAR-VASO_0060736	3 month-Interim Stability Summary Vasostrict pH 3.8 Acetate Buffer, Single Dose (Stock # 2002501)		H, A, DUP, R, F, 403
PTX-0264		PAR-VASO_0061004	PAR-VASO_0061004	Par Spreadsheet with Vasostrict Reformulation Information		H, A, R, F, 403, E
PTX-0265		PAR-VASO_0061005	PAR-VASO_0061005	Par Spreadsheet with Sample name and conditions		H, A, R, F, 403, E
PTX-0266	2015-10-16	PAR-VASO_0062982	PAR-VASO_0062994	Tabulated Stability Data through 3 Month Interval		H, A, DUP, R, F, 403
PTX-0267	2016-02-05	PAR-VASO_0066728	PAR-VASO_0066823	Vasostrict, 20 Units per 1ml Master Batch Record	Park Exhibit 12	H, R, 403
PTX-0268		PAR-VASO_0067647	PAR-VASO_0067659	Stability Results NDA 204485, Sequence # 0059, Supplement S-004		H, A, Dup, R, 403, F
PTX-0269	2012-09-25	PAR-VASO_0072228	PAR-VASO_0072245	Pitressin (Vasopressin Injection USP) Labeling Information		H
PTX-0270		PAR-VASO_0072472	PAR-VASO_0072502	Pitressin 2.3.P Drug Product Stability	English Exhibit 6	H, E
PTX-0271	2012-06-27	PAR-VASO_0073573	PAR-VASO_0073583	Product Development Report DEV-12-033R		H, A, Dup, R, F, 403
PTX-0272	2014-11-22	PAR-VASO_0081195	PAR-VASO_0081292	Vasostrict, 20 Units per 1ml Master Batch Record	Boesch Exhibit 4	H
PTX-0273		PAR-VASO_0082232	PAR-VASO_0082234	3.2.P.1 Vasostrict Description and Composition	Suketu Exhibit 6	H
PTX-0274	2012-04-16	PAR-VASO_0088184	PAR-VASO_0088212	Product Development Technical Report DEV-12-16 - Identification of Pitressin Impurities and Development of the AVP Impurity marker Solution D009-19		H, A, R, F, 403
PTX-0275		PAR-VASO_0089744	PAR-VASO_0089750	Bi, Mingda., Effect of buffer pH, buffer concentration and skin with or without enzyme inhibitors on the stability of [Arg8]-vasopressin, International Journal of Pharmaceutics 197 (2000) 87-93		H, A, R, F, 403
PTX-0276	2013-02-04	PAR-VASO_0089785	PAR-VASO_0089787	Email from V. Kannan to T. Kovalcik re: Pitressin NDA optimized product study		H, A, R, F, 403
PTX-0277		PAR-VASO_0089788	PAR-VASO_0089791	Comparison of Vasopressin Formulations		H, A, R, F, 403
PTX-0278	2015-09-29	PAR-VASO_0093612	PAR-VASO_0093671	Product Development Technical Report FRD-15-012 Vasostrict, 20 Units/mL, pH 3.8 Acetate Buffer, Single Dose (Preservative Free) (Stock #2002501)	Kannan Exhibit 29	H, A, Dup, R, F, 403
PTX-0279	2015-09-29	PAR-VASO_0093612	PAR-VASO_0093671	Product Development Technical Report FRD-15-012 Vasostrict, 20 Units/mL, pH 3.8 Acetate Buffer, Single Dose (Preservative Free) (Stock #2002501)	Vandse Exhibit 23	H, A, Dup, R, F, 403
PTX-0280	2015-09-29	PAR-VASO_0093612	PAR-VASO_0093671	Product Development Technical Report FRD-15-012 Vasostrict, 20 Units/mL, pH 3.8 Acetate Buffer, Single Dose (Preservative Free) (Stock #2002501)	Suketu Exhibit 11	H, A, Dup, R, F, 403
PTX-0281		PAR-VASO_0096366	PAR-VASO_0096447	Master Batch Record 2002532 Rev R002		H, A, E, R, F, 403
PTX-0282		PAR-VASO_0100092	PAR-VASO_0100188	Master Batch Record 2002501 Rev 9		H, A, R, F, 403, E
PTX-0283		PAR-VASO_0100393	PAR-VASO_0100491	Master Batch Record 2002525 Rev 7		H, A, R, F, 403
PTX-0284	2016-03-28	PAR-VASO_0101219	PAR-VASO_0101320	Master Batch Record 2002501, Revision 003		H, A, R, F, 403
PTX-0285	2016-01-28	PAR-VASO_0101219	PAR-VASO_0101320	Vasostrict, 20 units per 1 ML Master Batch Record	Chyall Exhibit 17	H, A, R, F, 403
PTX-0286	2014-10-09	PAR-VASO_0111795	PAR-VASO_0111795	E-mail from P. Dardaine to S. Ahmed et al. re SA Rochester Slides - 10/10/14		H, A, R, F, 403
PTX-0287		PAR-VASO_0111796	PAR-VASO_0111829	2014-10-10 Project Management Slides		H, A, R, F, 403
PTX-0288	2014-08-14	PAR-VASO_0112061	PAR-VASO_0112061	E-mail from P. Dardaine to S. Ahmed et al. re SA Rochester Slides - 8/15/14		H
PTX-0289		PAR-VASO_0112062	PAR-VASO_0112112	2014-08-15 Project Management Slides		H
PTX-0290	2014-07-17	PAR-VASO_0113001	PAR-VASO_0113001	E-mail from P. Dardaine to S. Ahmed et al. re SA Rochester Slides - 7/18/14		H, A, R, F, 403
PTX-0291		PAR-VASO_0113002	PAR-VASO_0113037	2014-07-18 Project Management Slides		H, A, R, F, 403
PTX-0292	2014-12-04	PAR-VASO_0113467	PAR-VASO_0113467	E-mail from P. Dardaine to S. Ahmed et al. re SA Rochester Slides - 12/5/14		H, A, R, F, 403
PTX-0293		PAR-VASO_0113468	PAR-VASO_0113500	2014-12-05 Project Management Slides		H, A, R, F, 403
PTX-0294	2011-09-19	PAR-VASO_0120243	PAR-VASO_0120263	SV 4200 Pitressin (Synthetic) USP, 20 units per 1 ML Master Batch Record	Boesch Exhibit 3	H, Dup
PTX-0295	2011-09-19	PAR-VASO_0120243	PAR-VASO_0120363	SV 4200 Pitressin USP Master Batch Record		H,Dup
PTX-0296	2015-05-07	PAR-VASO_0134068	PAR-VASO_0134068	E-mail from P. Dardaine to S. Ahmed et al. re SA Rochester Slides - 5/8/15		H, A, R, F, 403, E
PTX-0297		PAR-VASO_0134069	PAR-VASO_0134103	2015-05-08-Project Management Slides		H, A, R, F, 403
PTX-0298	2014-11-06	PAR-VASO_0135570	PAR-VASO_0135570	E-mail from P. Dardaine to S. Ahmed et al. re SA Rochester Slides - 11/7/14		H, A, R, F, 403
PTX-0299		PAR-VASO_0135571	PAR-VASO_0135604	2014-11-07 Project Management Slides		H, A, R, F, 403

EXHIBIT
23703

Par V. Eagle

Plaintiffs First Amended Exhibit List

PTX #	Date	Bates Begin	Bates End	Description	Depo. Exh No.	Objection(s)
PTX-0300	2015-01-15	PAR-VASO_0200879		Email from M. Kenney to S. Sanghvi re: Vasopressin Experimental Summary		H
PTX-0301		PAR-VASO_0200880	PAR-VASO_0200913	Vasopressin Experimental Summary	Chyall Exhibit 16	H, Dup
PTX-0302		PAR-VASO_0200880	PAR-VASO_0200913	Vasopressin Experimental Summary		H, Dup
PTX-0303	2015-06-10	PAR-VASO_0215523		Email from M. Kenney to S. Sanghvi re: vaso lab batch 4 month results	Kenney Exhibit 21	H
PTX-0304		PAR-VASO_0215524		Vasopressin Results Chart	Kenney Exhibit 22	H, I, E
PTX-0305		PAR-VASO_0219794	PAR-VASO_0219795	Pitressin (Vasopressin Injection, USP Synthetic Warning Label	Chyall Exhibit 15	H
PTX-0306		PAR-VASO_0226936	PAR-VASO_0227034	Spreadsheet		H, A, R, F, 403, E
PTX-0307		PAR-VASO_0226936	PAR-VASO_0227034	Spreadsheet		H, A, R, F, 403, E
PTX-0308		PAR-VASO_0230505	PAR-VASO_0230536	Table of Contents re: Stability	Chyall Exhibit 21	H, A, R, F, 403, E
PTX-0309	2013-10-18	PAR-VASO_0238720	PAR-VASO_0238757	Center for Drug Evaluation and Research, Chemistry Reviews	Park Exhibit 16	H, A, R, F, 403, E
PTX-0310	2015-05-01	PAR-VASO_0239795	PAR-VASO_0239802	USP Monograph 38, NF 33		H, A, R, F, 403, E
PTX-0311		PAR-VASO_0246222	PAR-VASO_0246429	Notebook No. 1281		H
PTX-0312		PAR-VASO_0246430	PAR-VASO_0246652	Notebook No. 1283		H
PTX-0313		PAR-VASO_0247613	PAR-VASO_0247819	Notebook No. 1277		H, A, R, F, 403
PTX-0314		PAR-VASO_0248169	PAR-VASO_0248172	Vasostrict Chart		H
PTX-0315		PAR-VASO_0248782	PAR-VASO_0249000	Notebook No. 1285		H, A, R, F, 403
PTX-0316		PAR-VASO_0291641	PAR-VASO_0291658	FDA, Analytical Procedures and Methods Validations for Drugs and Biologics: Guidance for Industry, Ctr. For Drug Evaluation and Research (July 2015)		H, A, R, 403, F, 26
PTX-0317		PAR-VASO_0291724	PAR-VASO_0291760	Guidance for Industry: Analytical Procedures and Methods Validation (Draft Guidance) August 2000		H, A, R, 403, F, 26
PTX-0318		PAR-VASO_0291761	PAR-VASO_0291775	Pharmaceutical Stress Testing: Predicting Drug Degradation (S.W. Baertschi, ed.) (2005)		H, A, R, 403, F, 26
PTX-0319		PAR-VASO_0291790	PAR-VASO_0291794	Webpage with information about patent examiner Christina Bradley		H, A, R, 403, F, 26, E
PTX-0320				A. Joshi, E. Rus, L. Kirsch, The degradation pathways of glucagon in acidic solutions, International Journal of Pharmaceutics 203 (2000)		H, A, R, 403, F, 26
PTX-0321	2020-01-10			Answer to Amended Counterclaims by Plaintiffs - In the Matter of Civil Docket # 1:18-cv-00823-CVC USDC of Delaware (Wilmington)		H, A, R, 403, F
PTX-0322				CV of Lee E. Kirsch		H, A, R, 403, F
PTX-0323				CV of Robert A. Minkin, Fache		H, A, R, 403, F
PTX-0324				CV of Zlatan Coralic, PharmD, BCPS		H, A, R, 403, F
PTX-0325	2019-03-22			Declaration of Zlatan Coralic	Coralic Exhibit 3	H
PTX-0326	2015-05-20			Declaration Under 37 CFR 1.32 by Inventor Sunil Vandse	Vandse Exhibit 10	Dup, H, I, E
PTX-0327	2015-05-20			Declaration Under 37 CFR 1.32 by Inventor Sunil Vandse	Vandse Exhibit 12	Dup, H, I, E
PTX-0328	2015-05-20			Declaration under 37 CFR by Inventor Sunil Vandse	Kannan Exhibit 40	Dup, H, I, E
PTX-0329	2015-05-20			Declaration under 37 CFR by Inventor Vinayagam Kannan	Kannan Exhibit 34	Dup, H, I, E
PTX-0330	2015-05-20			Declaration under 37 CFR by Inventor Vinayagam Kannan	Kannan Exhibit 36	Dup, H, I, E
PTX-0331	2018-08-06			Eagle Pharmaceuticals Inc.'s Answer to Complaint & Counterclaims - In the Matter of Civil Docket # 1:18-cv-00823-CVC USDC of Delaware (Wilmington)		H, R, 403
PTX-0332	2019-10-28			Eagle Pharmaceuticals, Inc.'s First Amended Answer to Complaint & Counterclaims		
PTX-0333	2018-09-27			Eagle Responses and Objections to Par's First Set of Requests for Production (Nos. 1-40)		H, A, R, 403
PTX-0334	2019-08-23			Eagle's First Supplemental Objections and Responses to Plaintiffs' First Set of Interrogatories (Nos. 1,8 and 9)		H, A, R, 403
PTX-0335	2019-09-27			Eagle's Objections and Responses to par's First Set of Requests for Admission (Nos. 1-25)		H, A, R, 403, F
PTX-0336	2018-09-27			Eagle's Objections to Plaintiffs' First Set of Interrogatories		H, A, R, F, 403, E
PTX-0337				Ex C - Materials Considered to Minkin Infringement Report		H, A, R, F, 403
PTX-0338				Ex. A Kirsch Infringement Reply Report Exhibit A - Materials Considered		H, A, R, F, 403
PTX-0339				Ex. B. FDA Guidance for Industry, ANDA Submissions - Content and Format June 2019		H, A, R, F, 403, 26
PTX-0340				Ex. C. FDA Guidance for Industry, ANDA's: Stability Testing of Drug Substances and Products: Qesitons and Answers: (May 2014)		H, A, R, F, 403, 26
PTX-0341				Ex. D. FDA Guidance for Industry, Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production		H, A, R, F, 403, 26

EXHIBIT
23209

Par V. Eagle

Plaintiffs First Amended Exhibit List

PTX #	Date	Bates Begin	Bates End	Description	Depo. Exh No.	Objection(s)
PTX-0342				Ex. E. Revised Calculations from Infringement Report Ex. C.		H, A, R, F, 403, E
PTX-0343				Exhibit A: Carmen A. Cross Resume	Cross Exhibit 4	
PTX-0344				Exhibit C to the Opening Expert Report of Dr. Lee Kirsch Regarding Infringement of the Asserted Patents		H, A, R, F, 403
PTX-0345	2019-12-22			Expert Report of Lee E. Kirsch regarding Validity and Enforceability	Kirsch 6	H, A, R, F, 403
PTX-0346	2019-11-14			Expert Report of Robert Minkin	Minkin Exhibit 1	H, A, R, F, 403
PTX-0347				H. Fresier and Q. Fernando, IONIC EQUILIBRIA IN ANALYTICAL CHEMISTRY, Wiley, New York (1963)		H, A, R, F, 403,
PTX-0348				Handbook of Stability Testing in Pharmaceutical Development; Regulations, Methodologies, and Best Practices(Kim Huyh-Ba) (2009)		H, A, R, F, 403, 1006
PTX-0349				Holmes et al., Science Review: Vasopressin and the cardiovascular system part 2—clinical physiology, Critical Care 2004, 8:15-23 (June 26, 2003)		H, A, R, F, 403, 26
PTX-0350				Holmes, et al., Science Review: Vasopressin and the cardiovascular system part 1—receptor physiology, Critical Care, 2003, 7:427-34 (June 26, 2003)		H, A, R, F, 403, 26
PTX-0351				Infringement Claim Chart for U.S. Patent No. 9,687,526		H, A, R, F, 403
PTX-0352				Infringement Claim Chart for U.S. Patent No. 9,744,209		H, A, R, F, 403
PTX-0353	2019-05-03			Joint Claim Construction Brief	Amiji Exhibit 13	H, R, F, 403
PTX-0354				Kirsch Opening Infringement Report Exhibit B - Materials Considered		H, A, R, F, 403
PTX-0355	2015-05-20			Office Action Summary	Vandse Exhibit 11	Dup, E
PTX-0356	2019-11-15			Opening Expert Report of Lee E. Kirsch regarding infringement	Kirsch 5	H, A, R, F, 403
PTX-0357	2019-12-27			Order Granting Stipulation of Dismissal filed by Plaintiffs - In the Matter of Civil Docket # 1:18-cv-00823-CVC USDC of Delaware (Wilmington)		R, H, 403
PTX-0358				Par Final Infringement Contentions, Par Pharm., Inc. v. Eagle Pharms. Inc (October 16, 2019)		H, A, R, F, 403
PTX-0359				Par Pharm., Inc. v. Eagle Pharms, Inc. No. 18-823-CFC. D.I. 71 (July 1 2019), Markman Order		
PTX-0360	2019-08-23			Par Pharmaceutical Inc, Par Sterile Products, LLC and Endo Par Innovation Co. LLC's Revised First Notice if Deposition of OSO	Woltering Exhibit 2	H, A, R, F, 403
PTX-0361	2019-08-23			Par Pharmaceutical Inc, Par Sterile Products, LLC and Endo Par Innovation Co. LLC's Revised First Notice of Deposition of AMRI	Woltering Exhibit 1	H, A, R, F, 403
PTX-0362				Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC's Revised First Notice of Deposition of Eagle Pharmaceuticals Inc.	Hepner Exhibit 1	H, A, R, F, 403, Dup
PTX-0363	2019-08-23			Par Pharmaceuticals and Endo Par Revised First Notice of Deposition of Eagle Pharmaceuticals	Romito Exhibit 1	H, A, R, F, 403, Dup
PTX-0364	2019-08-23			Par Pharmaceuticals, Inc. Par Sterile Products, LLC's Revised First Notice of Deposition of Amri	Aungst Exhibit 1	H, A, R, F, 403, Dup
PTX-0365	2019-08-23			Par Pharmaceuticals, Inc. Par Sterile Products, LLC's Revised First Notice of Deposition of Oso	Aungst Exhibit 2	H, A, R, F, 403, Dup
PTX-0366	2018-08-27			Plaintiffs' Answer to Counterclaim - In the Matter of Civil Docket # 1:18-cv-00823-CVC USDC of Delaware (Wilmington)		H, A, R, F, 403, Dup
PTX-0367	2018-05-31			Plaintiffs' Complaint for Patent Infringement - In the Matter of Civil Docket # 1:18-cv-00823-CVC USDC of Delaware (Wilmington)		H, A, R, F, 403
PTX-0368	2019-10-22			Plaintiffs' Fourth Supplemental Objections and Responses to Eagle Pharmaceuticals Inc.'s Interrogatories (Nos 13, 23)		H, A, R, F, 403
PTX-0369	2020-01-20			Reply Expert of Robert Minkin	Minkin Exhibit 2	H, A, R, F, 403
PTX-0370	2020-01-20			Reply Expert Report of Lee E. Kirsch regarding infringement	Kirsch 7	H, A, R, F, 403
PTX-0371	2020-01-20			Reply Expert Report of Zlatan Coralic regarding infringement	Coralic Exhibit 2	H, A, R, F, 403
PTX-0372	2015-08-14			Response to Action: Peptide Congeners with Polymer Excipients	Kannan Exhibit 30	Dup, E
PTX-0373	2015-11-24			Response to Final Office Action and Request for Continued Examination re: Vasopressin Formulations for use in Treatment of Hypotension	Kannan Exhibit 33	Dup, E

EXHIBIT
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Plaintiffs First Amended Exhibit List

PTX #	Date	Bates Begin	Bates End	Description	Depo. Exh No.	Objection(s)
PTX-0374				Stratton, Lewis, Controlling Deamidation Rates in a Model Peptide: Effects of Temperature, Peptide Concentration, and Additives, Journal of Pharmaceutical Sciences Vol. 90, No. 12 (December 2001) 2141-2148		H, A, R, F, 403
PTX-0375	2019-04-16			Supplemental Declaration of Zlatan Coralic	Coralic Exhibit 4	H, A, R, F, 403
PTX-0376	2015-10-21			United States Patent Application NO. 14717877 Office Action Summary	Kannan Exhibit 31	Dup
PTX-0377	2015-05-20			United States Patent Application NO. 14717877 Office Action Summary	Kannan Exhibit 35	Dup
PTX-0378	2009-05-01			USP 32 (2009)	Amiji Exhibit 10	
PTX-0379	2012-05-01			USP 35 (2012) <791>	Amiji Exhibit 9	H, A, R, F, 403
PTX-0380				USP 36 (2013) <659>		H, A, R, F, 403, 26
PTX-0381				Wang, Wei, Instability, stabilization and formulation of liquid protein pharmaceutical, International Journal of Pharmaceutics 185 (1999) 129-188		H, A, R, F, 403
PTX-0382				Vasostrict Label		H, A
PTX-0383	2013-06-17	AMRIVAS0116902	AMRIVAS0116913	Vasopressin Injection, USP, AMRI Stability Data for SVA001.002.003		R, 403, F, E
PTX-0384	2013-06-17	AMRIVAS0116914	AMRIVAS0116923	Vasopressin Injection, USP, AMRI Stability Data for SVA001.002.003		R, 403, F, E
PTX-0385	2019-10-16	AMRIVAS0117038	AMRIVAS0117041	Vasopressin Injection, USP, AMRI Stability Data for SVA009.5I+5U		R, 403
PTX-0386	2019-12-11	AMRIVAS0117062	AMRIVAS0117065	Vasopressin Injection, USP, AMRI Stability Data for SVA009.5I+5U		R, 403
PTX-0387	2019-10-09	AMRIVAS0117066	AMRIVAS0117069	Vasopressin Injection, USP, AMRI Stability Data for SVA004.25I+25U		R, 403
PTX-0388	2019-10-09	AMRIVAS0117072	AMRIVAS0117075	Vasopressin Injection, USP, AMRI Stability Data for SVA004.5I+5U		R, 403
PTX-0389	2019-10-23	AMRIVAS0117076	AMRIVAS0117079	Vasopressin Injection, USP, AMRI Stability Data for SVA005.25I+25U		R, 403
PTX-0390	2019-10-23	AMRIVAS0117084	AMRIVAS0117087	Vasopressin Injection, USP, AMRI Stability Data for SVA005.5I+5U		R, 403
PTX-0391	2019-10-23	AMRIVAS0117088	AMRIVAS0117091	Vasopressin Injection, USP, AMRI Stability Data for SVA006.25I+25U		R, 403
PTX-0392	2019-10-23	AMRIVAS0117096	AMRIVAS0117099	Vasopressin Injection, USP, AMRI Stability Data for SVA006.5I+5U		R, 403
PTX-0393	2019-09-07	AMRIVAS0117100	AMRIVAS0117100	OSOBIO Project Notebook Document Number: STA-PJN-0029, SVA007/8 - 1M, Ver. 3		R, 403, F
PTX-0394	2019-10-02	AMRIVAS0117101	AMRIVAS0117102	OSOBIO Project Notebook Document Number: STA-PJN-0029, SVA004.6M, Ver. 3		R, 403, F
PTX-0395	2019-10-10	AMRIVAS0117103	AMRIVAS0117104	OSOBIO Project Notebook Document Number: STA-PJN-0029, SVA009 - 1M, Ver. 3		R, 403, F
PTX-0396	2019-10-31	AMRIVAS0117105	AMRIVAS0117106	OSOBIO Project Notebook Document Number: STA-PJN-0029, SVA007/8 - 3M, Ver. 3		R, 403, F
PTX-0397	2019-11-13	AMRIVAS0117107	AMRIVAS0117107	OSOBIO Project Notebook Document Number: STA-PJN-0029, SVA009.2M, Ver. 3		R, 403, F
PTX-0398	2019-12-10	AMRIVAS0117108	AMRIVAS0117109	OSOBIO Project Notebook Document Number: STA-PJN-0029, SVA009.3M, Ver. 3		R, 403, F
PTX-0399	2020-03-11	AMRIVAS0117128	AMRIVAS0117129	OSOBIO Project Notebook Document Number: STA-PJN-0029, SVA009.6M, Ver. 3		R, 403, F
PTX-0400	2020-03-19	AMRIVAS0117134	AMRIVAS0117137	AMRI Vasopressin Injection USP Project #: PD SVA-07, Storage Condition: 5C Inverted - Lot Number: SVA009.5I		R, 403, F
PTX-0401	2020-01-19	AMRIVAS0117138	AMRIVAS0117139	OSO BioPharmaceuticals Manufacturing, LLC Laboratory Notebook Excerpts Regarding Vasopressin Injection, USP Samples SVA005/006 - 9M (Document No. STA-PJN-0029) (Version: 3.0)		R, 403, F
PTX-0402	2020-01-07	AMRIVAS0117150	AMRIVAS0117151	OSO BioPharmaceuticals Manufacturing, LLC Laboratory Notebook Excerpts Regarding Vasopressin Injection, USP Sample SVA004.9M (Document No. STA-PJN-0029) (Version: 3.0)		R, 403, F
PTX-0403	2020-04-02	AMRIVAS0117172	AMRIVAS0117173	OSO BioPharmaceuticals Manufacturing, LLC Laboratory Notebook Excerpts Regarding Vasopressin Injection, USP Sample SVA004.12M (Document No. STA-PJN-0029) (Version: 3.0)		R, 403, F
PTX-0404	2020-05-09	AMRIVAS0117176	AMRIVAS0117177	OSO BioPharmaceuticals Manufacturing, LLC Laboratory Notebook Excerpts Regarding Vasopressin Injection, USP Sample SVA005/7/8.9M (Document No. STA-PJN-0029) (Version: 3.0)		R, 403, F
PTX-0405	2019-08-27	EAGLEVAS0047242	EAGLEVAS0047248	Vasopressin Injection, USP Stability Analysis, A Statistical Evaluation of pH		H, R, 403, F
PTX-0406	2019-11-14			Expert Report of Zlatan Coralic, Pharm.D., BCPS regarding Infringement	Coralic 1	H, A, R, F, 403
PTX-0407	2020-02-03	AMRIVAS0117118	AMRIVAS0117119	OSO BioPharmaceuticals Manufacturing, LLC Laboratory Notebook Excerpts Regarding Vasopressin Injection, USP Sample SVA007/8.6M (Document No. STA-PJN-0029) (Version: 3.0)		R, 403, F
PTX-0408	3/xx/1980	AMPHPA0006054	AMPHPA0006080	Gordon L. Flynn, "Buffers - pH Control within Pharmaceutical Systems," PDA J. Pharm. Sci. and Tech. 34 139-162 (1980)		H, A, R, F, 403, 26
PTX-0409	xx/xx/2013	AMPHPA0006136	AMPHPA0006184	Pharmaceutical Formulation Development of Peptides and Proteins (2d ed.) (L. Hovgaard, S. Forkjaer, M. van de Weert eds. 2013)		H, A, R, F, 403, 26

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Plaintiffs First Amended Exhibit List

PTX #	Date	Bates Begin	Bates End	Description	Depo. Exh No.	Objection(s)
PTX-0410	2015-05-01	AMPHPA0006744	AMPHPA0006747	USP Vasopressin Injection USP 38		H, A, R, F, 403, 26
PTX-0411	2017-04-28	PAR-VASO_0070200	PAR-VASO_0070289	Stability Data		H, R, 403, F
PTX-0412	2013-05-17	PAR-VASO_0077369	PAR-VASO_0077369	JHP May 2013 Letter to FDA, Request for Reconsideration of Proprietary Name		H, R, 403, F
PTX-0413	2013-02-04	PAR-VASO_0089792	PAR-VASO_0089792	Email from Kannan to Bergren re Pitressin Comparison		H, A, R, 403, F
PTX-0414	2013-02-04	PAR-VASO_0089793	PAR-VASO_0089796	Comparison of Vasopressin Formulations		H, A, F
PTX-0415				Unused Number		26, A, R, F, 403
PTX-0416				Unused Number		26, A, R, F, 403
PTX-0417	xx/xx/1993	PAR-VASO_0298219	PAR-VASO_0298224	Kirsch, L. E., Riggan, R., Gearhart, D., LeFeber, D., Lytle, D., "In-process Protein Degradation by Exposure to Trace Amounts of Sanitizing Agents," Journal of Parenteral Science and Technology, 47(4):155-160 (1993)		H, A, R, F, 403, 26
PTX-0418		PAR-VASO_0298225	PAR-VASO_0298228	Kirsch, L. E., Notari, R., "Theoretical Basis for the Detection of General-Base Catalysis in the Presence of Predominating Hydroxide Catalysis," Journal of Pharmaceutical Sciences, 73(6):724-727		H, A, R, F, 403, 26
PTX-0419	xx/xx/1995	PAR-VASO_0298229	PAR-VASO_0298302	Joost J. M. Holthuis and Reinoud J. Driebergen, "Chromatographic Techniques for the Characterization of Proteins," in Physical Methods to Characterize Pharmaceutical Protein, eds. James N. Herron, Wim Jiskoot, Daan J.A. Crommelin, Plenum Press, New York, 1995		H, A, R, F, 403, 26
PTX-0420		PAR-VASO_0298412	PAR-VASO_0298450	Jens Brange and Lotte Langkjaer, "Insulin Structure and Stability," in Stability and Characterization of Protein and Peptide Drugs: Case Histories, eds. Y. John Wang and Rodney Pearlman, Plenum Press, New York, 19		H, A, R, F, 403, 26
PTX-0421		PAR-VASO_0298451	PAR-VASO_0298599	Nail, S. L., & Akers, M. J. (2002). Development and manufacture of protein pharmaceuticals. New York: Kluwer Academic/Plenum Publishers.		H, A, R, F, 403, 26
PTX-0422		PAR-VASO_0298600	PAR-VASO_0298725	James E. De Muth, Basic Statistics and Pharmaceutical Statistical Application, 2nd, Chapman & Hall/CRC, Boca Raton, 2006		H, A, R, F, 403, 26
PTX-0423		PAR-VASO_0298726	PAR-VASO_0298740	C. Lawrence, A. Reilly, "Maximum Likelihood Estimation of Subsequence Conservation," J. Theor. Biol., 113 425-439 (1985)		H, A, R, F, 403, 26
PTX-0424	2020-06-19	EAGLEVAS0058589	EAGLEVAS0058595	Letter from FDA to Eagle re ANDA received for review on 3/23/18		H, R, 403, E
PTX-0425	2020-06-30	EAGLEVAS0058607	EAGLEVAS0058618	Letter from Eagle to FDA re Post-Complete Response Letter Meeting Request		H, R, 403, F
PTX-0426	2020-07-23	EAGLEVAS0058655	EAGLEVAS0058660	Preliminary Response to Meeting Questions		H, R, 403, E
PTX-0427	2020-07-28	EAGLEVAS0059112	EAGLEVAS0059115	ANDA 211538 - Vasopressin Injection, USP, Post-Complete Response Meeting Follow-up Inquiry-2		H, R, 403, E, F
PTX-0428	2020-08-28	EAGLEVAS0059116	EAGLEVAS0059119	ANDA 211538 Correspondence Post_CRL Meeting		H, R, 403, F
PTX-0429	2020-07-30	EAGLEVAS0059120	EAGLEVAS0059139	Letter from Eagle to FDA re General Correspondence Follow-up Inquiry for July 27, 2020 Post-Complete Response Letter		H, R, 403, F
PTX-0430	2020-08-04	EAGLEVAS0059140	EAGLEVAS0059144	RE_ ANDA 211538 - Vasopressin Injection, USP, Post-Complete Response Meeting Follow-up Inquiry-2.pdf		H, A, R, F, 403
PTX-0431	Undated	EAGLEVAS0059152	EAGLEVAS0059152	Carton, 25 x 1mL Multiple Dose Vials		R, 403
PTX-0432	Undated	EAGLEVAS0059153	EAGLEVAS0059156	Explanation of differences, Carton vial side by side		R, 403
PTX-0433	2020-09-01	EAGLEVAS0059158	EAGLEVAS0059166	Proposed package insert, September 2020		R, 403
PTX-0434	Undated	EAGLEVAS0059172	EAGLEVAS0059172	Carton, 25 x 1mL Multiple Dose Vials		R, 403
PTX-0435	Undated	EAGLEVAS0059173	EAGLEVAS0059173	1mL Multiple Dose Vial label		R, 403
PTX-0436	2020-09-24	EAGLEVAS0059231	EAGLEVAS0059262	Letter from Eagle to FDA re Resubmission - Major Complete Response Amendment Pharmaceutical Quality/Labeling		H, R, 403, F
PTX-0437	2020-09-10	EAGLEVAS0059264	EAGLEVAS0059264	Field Copy Certification		R, 403
PTX-0438	Undated	EAGLEVAS0059266	EAGLEVAS0059398	Module 2 Supplement: Question-based Review of Drug Product		R, 403
PTX-0439	Undated	EAGLEVAS0059399	EAGLEVAS0059447	2.3 Introduction to the Quality Overall Summary		R, 403
PTX-0440	2020-09-08	EAGLEVAS0059448	EAGLEVAS0059469	Eagle Vasopressin Impurities EpiVax HLA Class II Binding Analysis Report		H, R, 403, F
PTX-0441	2020-09-24	EAGLEVAS0059470	EAGLEVAS0059659	Eagle Pharmaceuticals, Inc. Technical Report		R, 403
PTX-0442	Undated	EAGLEVAS0059660	EAGLEVAS0059660	Module 3 3.2.P.2 Pharmaceutical Development - List of documents for studies conducted to support CRL response		R, 403
PTX-0443	Undated	EAGLEVAS0059734	EAGLEVAS0059749	Module 3 3.2.P.3.4 Controls of Critical Steps and Intermediates		R, 403
PTX-0444	Undated	EAGLEVAS0059750	EAGLEVAS0059751	Module 3 3.2.P.3.1 Manufacturers		R, 403

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Par V. Eagle

Plaintiffs First Amended Exhibit List

PTX #	Date	Bates Begin	Bates End	Description	Depo. Exh No.	Objection(s)
PTX-0445	2020-09-12	EAGLEVAS0059752	EAGLEVAS0059777	Vasopressin Injection USP, In-Process Test Procedure STA-IPX-0153		R, 403
PTX-0446	Undated	EAGLEVAS0059778	EAGLEVAS0059781	Module 3 3.2.P.5.1 Specifications		R, 403
PTX-0447	Undated	EAGLEVAS0059782	EAGLEVAS0059783	Module 3 3.2.P.5.2 Analytical Procedures		R, 403
PTX-0448	2020-08-31	EAGLEVAS0059784	EAGLEVAS0059795	Primera Limit Test of Vasopressin Trimer in Vasopressin Drug Product by LC-MS/MS		H, R, F, 403
PTX-0449	2020-09-12	EAGLEVAS0059796	EAGLEVAS0059832	sta-epx-0119.pdf		R, 403
PTX-0450	2020-08-31	EAGLEVAS0059833	EAGLEVAS0059866	Primera Method Validation Report		H, R, F, 403
PTX-0451	Undated	EAGLEVAS0059867	EAGLEVAS0059869	3.2.P.5.3 Validation of Analytical Procedures		R, 403
PTX-0452	Undated	EAGLEVAS0059870	EAGLEVAS0059881	3.2.P.5.5 Characterization of Impurities		R, 403
PTX-0453	Undated	EAGLEVAS0059882	EAGLEVAS0059902	3.2.P.5.6 Justification of Specifications		R, 403
PTX-0454	Undated	EAGLEVAS0059929	EAGLEVAS0059932	3.2.P.8.2 Post-Approval Stability Protocol and Stability Commitment		R, 403
PTX-0455	Undated	EAGLEVAS0059933	EAGLEVAS0059938	3.2.P.8.3 Stability Data		R, 403
PTX-0456	Undated	EAGLEVAS0059986	EAGLEVAS0060015	3.2.P.8.1 Stability Summary and Conclusion		R, 403
PTX-0457	Undated	EAGLEVAS0060016	EAGLEVAS0060022	3.2.S.3.1 Elucidation of Structure and Other Characteristics		R, 403
PTX-0458	2020-09-03	EAGLEVAS0060023	EAGLEVAS0060134	Eagle Pharmaceuticals, Inc. Technical Report		R, 403
PTX-0459	Undated	EAGLEVAS0060135	EAGLEVAS0060153	3.2.S.3.2 Impurities		R, 403
PTX-0460	Undated	EAGLEVAS0060154	EAGLEVAS0060157	3.2.S.4.1 Specification		R, 403
PTX-0461	Undated	EAGLEVAS0060158	EAGLEVAS0060159	3.2.S.4.2 Analytical Procedures		R, 403
PTX-0462	2020-09-12	EAGLEVAS0060160	EAGLEVAS0060217	Acceptance of Criteria for Vasopressin API, USP STA-ATX-0126		R, 403
PTX-0463	Undated	EAGLEVAS0060296	EAGLEVAS0060297	3.2.S.4.3 Validation of Analytical Procedures		R, 403
PTX-0464	Undated	EAGLEVAS0060298	EAGLEVAS0060306	3.2.S.4 Justification of Specification		R, 403
PTX-0465	2020-09-26	EAGLEVAS0060332	EAGLEVAS0060334	Amendment Acknowledgement Letter		H, R, 403, F
PTX-0466	2020-05-08			Revised Supplemental Expert Report of Lee E. Kirsch, Ph.D Regarding Infringement		H, A, R, F, 403
PTX-0467				Exhibit 1 - Guidance for Industry Q1E Evaluation of Stability Data June 2004		H, A, R, F, 403
PTX-0468				Exhibit 2 - ICH Harmonised Tripartite Guideline Evaluation for Stability Data Q1E February 6 2003		H, A, R, F, 403
PTX-0469	3/xx/2016	PAR-VASO_0014613	PAR-VASO_0014618	NDA 204485/S-003 Approval Letter		H, A, R, F, 403
PTX-0470		PAR-VASO_0298746	PAR-VASO_0298750	FDA Emergency Preparedness and Response: Expiration Dating Extension		H, A, R, F, 403, 26
PTX-0471		PAR-VASO_0089820	PAR-VASO_0089821	Comparison of Vasopressin Formulations		H, A, F
PTX-0472	2020-12-11			Supplemental Expert Report of Lee E. Kirsch, Ph.D Regarding Validity		H, A, R, F, 403
PPX-001				Placeholders for Plaintiffs' Physical Exhibits		26, A, R, F, 403
PPX-002				Placeholders for Plaintiffs' Physical Exhibits		26, A, R, F, 403
PPX-003				Placeholders for Plaintiffs' Physical Exhibits		26, A, R, F, 403
PPX-004				Placeholders for Plaintiffs' Physical Exhibits		26, A, R, F, 403
PPX-005				Placeholders for Plaintiffs' Physical Exhibits		26, A, R, F, 403
PPX-006				Placeholders for Plaintiffs' Physical Exhibits		26, A, R, F, 403
PPX-007				Placeholders for Plaintiffs' Physical Exhibits		26, A, R, F, 403
PPX-008				Placeholders for Plaintiffs' Physical Exhibits		26, A, R, F, 403
PPX-009				Placeholders for Plaintiffs' Physical Exhibits		26, A, R, F, 403

Eagle's Objection Code	
CODE	OBJECTION
A	Fed. R. Evid. 901 - Requires proof of authenticity as a condition precedent to its admissibility
DEM	Demonstrative Only
DUP	Duplication of Another Exhibit
E	Mischaracterization in Description
F	Fed. R. Evid. 602 - No Foundation
H	Fed. R. Evid. 801 & 802 - Hearsay
I	Illegible (partly or wholly)
IC	Improper compilation
IN	Fed. R. Evid. 106 - Incomplete
NT	No Certified Translation
R	Fed. R. Evid. 402 - Not Relevant
RD	Redaction Required
26	Fed. R. Civ. P. 26 - Not timely disclosed
403	Fed. R. Evid. 403 - Any relevance substantially outweighed by confusion, prejudice or waster of time
1006	Fed. R. Evid. 1006 - Voluminous document requires summary

EXHIBIT 8

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

PAR PHARMACEUTICAL, INC.,)	
PAR STERILE PRODUCTS, LLC, and)	
ENDO PAR INNOVATION)	
COMPANY, LLC,)	
)	C.A. No. 18-823-CFC
Plaintiffs,)	
)	
v.)	
)	
EAGLE PHARMACEUTICALS INC.,)	
)	
Defendant.)	

DEFENDANT'S EXHIBIT LIST

Defendant Eagle Pharmaceuticals Inc. reserves its right to incorporate by reference into its Exhibit List any exhibit listed by Plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC (collectively “Plaintiffs”) on Plaintiffs’ Exhibit List. Eagle reserves its right to amend, modify, or supplement its Exhibit List throughout the balance of this case in response to case developments including but not limited to Plaintiffs’ Exhibit List, Plaintiffs’ objections, and/or further streamlining of the case. Eagle also reserves the right to supplement or modify its Exhibit List in response to rulings by the Court (including on any motions) or upon settlement of any party. Eagle also reserves its right to add demonstratives to its Exhibit List. Eagle agrees to exchange demonstratives with Plaintiffs in accordance with the procedures agreed upon by the parties in the Joint Pretrial Order.

U.S. DISTRICT COURT FOR THE DISTRICT OF DELAWARE
PAR PHARMACEUTICAL, INC., et al. v. EAGLE PHARMACEUTICALS INC.

C.A. No. 18-cv-00823-CFC

DEFENDANT EAGLE PHARMACEUTICALS INC.'s TRIAL EXHIBIT LIST

EXHIBIT NO.	DATE	DESCRIPTION	BEG BATES NO.	END BATES NO.	OBJECTIONS
DTX-001	6/28/2016	U.S. Patent No. 9,375,478 to Kenney et al.	PAR-VASO-0000001	PAR-VASO-0000033	401, 402, 403
DTX-002	6/27/2017	Moved to Joint Exhibit List (JTX-4)	PAR-VASO-0000034	PAR-VASO-0000113	
DTX-003	8/29/2017	Moved to Joint Exhibit List (JTX-5)	PAR-VASO-0000114	PAR-VASO-0000197	
DTX-004	8/29/2017	U.S. Patent No. 9,744,239 to Kenney et al.	PAR-VASO-0000198	PAR-VASO-0000231	401, 402, 403
DTX-005	9/5/2017	Moved to Joint Exhibit List (JTX-6)	PAR-VASO-0000232	PAR-VASO-0000314	
DTX-006	4/10/2018	U.S. Patent No. 9,937,223 to Kenney et al.	PAR-VASO-0000315	PAR-VASO-0000421	401, 402, 403
DTX-007	6/28/2016	File History of U.S. Patent No. 9,375,478 to Kenney et al. (Application No. 14/717,882)	PAR-VASO-0000422	PAR-VASO-0002628	401, 402, 403
DTX-008	6/27/2017	Moved to Joint Exhibit List (JTX-7)	PAR-VASO-0002629	PAR-VASO-0005399	
DTX-009	8/29/2017	Moved to Joint Exhibit List (JTX-8)	PAR-VASO-0005400	PAR-VASO-0006452	
DTX-010	8/29/2017	File History of U.S. Patent No. 9,744,239 to Kenney et al. (Application No. 14/717,877)	PAR-VASO-0006453	PAR-VASO-0009318	
DTX-011	9/5/2017	Moved to Joint Exhibit List (JTX-9)	PAR-VASO-0009319	PAR-VASO-0010365	401, 402, 403
DTX-012	4/10/2018	File History of U.S. Patent No. 9,937,223 to Kenney et al. (Application No. 15/606,442)	PAR-VASO-0010366	PAR-VASO-0014205	401, 402, 403
DTX-013	6/22/2015	Assignment of U.S. Patent No. 9,375,478 to Par Pharmaceutical, Inc., recorded at reel 035877 frame 0334 on June 22, 2015	PAR-VASO_0108283	PAR-VASO_0108289	
DTX-014	10/26/2016	Moved to Joint Exhibit List (JTX-11)	PAR-VASO_0108300	PAR-VASO_0108307	
DTX-015	4/19/2017	Moved to Joint Exhibit List (JTX-10)	PAR-VASO_0108290	PAR-VASO_0108299	
DTX-016	4/20/2017	Moved to Joint Exhibit List (JTX-14)	PAR-VASO_0108333	PAR-VASO_0108341	
DTX-017	3/2/2017	Moved to Joint Exhibit List (JTX-13)	PAR-VASO_0108321	PAR-VASO_0108326	
DTX-018	6/22/2015	Assignment of U.S. Patent No. 9,744,239 to Par Pharmaceutical, Inc., recorded at reel 035877 frame 0318 on June 22, 2015	PAR-VASO_0108314	PAR-VASO_0108320	401, 402, 403
DTX-019	3/2/2017	Moved to Joint Exhibit List (JTX-12)	PAR-VASO_0108308	PAR-VASO_0108313	
DTX-020	6/16/2017	Assignment of U.S. Patent No. 9,937,223 to Par Pharmaceutical, Inc., recorded at reel 042734 frame 0093 on June 16, 2017	PAR-VASO_0108327	PAR-VASO_0108332	401, 402, 403
DTX-021	6/8/2017	Moved to Joint Exhibit List (JTX-15)	PAR-VASO_0108342	PAR-VASO_0108373	
DTX-022	6/10/2019	Eagle Pharmaceuticals Inc.'s Notice of Deposition Pursuant to Fed. R. Civ. P. 30(b)(6) to Plaintiffs			401, 402, 403, 801, 802, AA
DTX-023	9/19/2011	JHP Pharmaceuticals, LLC Master Batch Record: SV 4200 Pitressin (Synthetic) USP, 20 Units per 1 mL (Stock No. 2000179) (Revision Code: 023)	PAR-VASO_0120243	PAR-VASO_0120363	
DTX-024	10/22/2014	JHP Pharmaceuticals, LLC Master Batch Record: Vasostrict™, 20 Units per 1 mL (Stock No. 2002132) (Revision Code: 008)	PAR-VASO_0081195	PAR-VASO_0081292	
DTX-025	9/16/2011	Letter from G. Vasquez of JHP Pharmaceuticals, LLC to Drs. M. Parks and N. Stockbridge of the FDA Enclosing Pre NDA Meeting Package re Pitressin® (vasopressin injection, USP), Synthetic	PAR-VASO_0058258	PAR-VASO_0058372	401, 402, 403, 801, 802
DTX-026		JHP Pharmaceuticals NDA Module: 2.3.P Drug Production - Pitressin® (NDA No. 204485)	PAR-VASO_0072472	PAR-VASO_0072502	
DTX-027	8/19/2014	Par Sterile Products, LLC Memorandum from A. Gloster to J. Zebelian re 2014 APR Stability Information for Pitressin	PAR-VASO_0088553	PAR-VASO_0088596	
DTX-028	3/11/2010	Compilation of Certificates of Analysis Prepared by Various Laboratories Regarding Vasopressin and Arginine Vasopressin Products	PAR-VASO_0090471	PAR-VASO_0090483	801, 802, 901, 902, multiple separate documents

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EXHIBIT NO.	DATE	DESCRIPTION	BEG BATES NO.	END BATES NO.	OBJECTIONS
DTX-029	11/6/2014	Par Pharmaceutical, Inc. Product Specification-Release Report: Vasostrict™ (vasopressin injection, USP) 20 units per 1 mL (Stock No. 2002132) (Version: 6.0)	PAR-VASO_0028731	PAR-VASO_0028743	401, 402, 403
DTX-030	4/17/2014	NDA Approval Letter from Dr. N. Stockbridge of the FDA to G. Vasquez of Par Sterile Products, LLC Enclosing Vasostrict™ (vasopressin injection) Prescribing Information (revised: 04/2014) and Package Labeling (Reference ID: 3491207)	PAR-VASO_0015573	PAR-VASO_0015586	801, 802
DTX-031	1/27/2012	JHP Pharmaceuticals, LLC Master Batch Record: SV 4200 Pitressin (Synthetic) USP, 20 Units per 1 mL (Batch No. 310571F) (Revision Code: 001)	PAR-VASO_0247003	PAR-VASO_0247057	
DTX-032	1/27/2012	JHP Pharmaceuticals, LLC Master Batch Record: SV 4200 Pitressin (Synthetic) USP, 20 Units per 1 mL (Batch No. 310571F) (Revision Code: 001)	PAR-VASO_0247058	PAR-VASO_0247072	
DTX-033		Par Pharmaceutical, Inc. Product Development Technical Report (No. FRD-16-001): <i>Vasostrict, 20 Units/mL, pH 3.8 Acetate Buffer, Multiple Dose (Stock # 2002525)</i>	PAR-VASO_0030979	PAR-VASO_0031015	
DTX-034	3/16/2009	JHP Pharmaceuticals, LLC Research Report (No. 703-00159): <i>Analytical Method Validation Report for the Determination of Vasopressin and Impurities in Pitressin by Gradient HPLC</i>	PAR-VASO_0104961	PAR-VASO_0105008	
DTX-035	10/3/2019	Notice of Subpoena Directed As to Michelle Bonomi-Huvala to Testify at a Deposition in a Civil Action			401, 402, 403, 801, 802
DTX-036	4/2014	Vasostrict™ (vasopressin injection) Prescribing Information (revised: 04/2014) (Reference ID: 3491207)	PAR-VASO-0008349	PAR-VASO_0008356	
DTX-037	11/22/2010	Email from K. Goscinski to C. English re RE: JHP - Vasopressin API	PAR-VASO_0241689	PAR-VASO_0241695	401, 402, 403, 801, 802
DTX-038	11/12/2010	Letter from S. Richardson of JHP Pharmaceuticals, LLC to D. Stanback of the FDA re Entry No. 435-1024270-4 (2300TU) and 435-1024392-6 (460TU); End Use for Product: Synthetic Arginine Vasopressin, USP and PITRESSIN (vasopressin injection, USP synthetic) Grandfathered Status	PAR-VASO_0241702	PAR-VASO_0241796	401, 402, 403, 801, 802
DTX-039	11/16/2011	Letter from J. Johnson of the FDA to G. Vasquez of JHP Pharmaceuticals, LLC Enclosing Meeting Minutes of Pre-NDA Telephone Conference dated October 17, 2011	PAR-VASO_0037497	PAR-VASO_0037515	401, 402, 403, 801, 802
DTX-040		Pitressin® (vasopressin injection, USP) Synthetic Prescribing Information	PAR-VASO_0072228	PAR-VASO_0072245	401, 402, 403, 901, 902
DTX-041		JHP Pharmaceuticals NDA Submission: Annotated Prescribing Information - Pitressin® (NDA No. 204485)	PAR-VASO_0072190	PAR-VASO_0072206	
DTX-042		JHP Pharmaceuticals NDA Module: 2.5 Clinical Overview - Pitressin® (NDA No. 204485)	PAR-VASO_0072526	PAR-VASO_0072689	
DTX-043		JHP Pharmaceuticals NDA Module: 3.2.P.5.6 Justification of Specifications Pitressin® (NDA No. 204485)	PAR-VASO_0073366	PAR-VASO_0073369	401, 402, 403
DTX-044		JHP Pharmaceuticals NDA Module: 3.2.P.5.1 Specifications - Pitressin® (NDA No. 204485)	PAR-VASO_0078037	PAR-VASO_0078037	401, 402, 403
DTX-045		JHP Pharmaceuticals NDA Module: 3.2.P.8.3 Stability Data - Pitressin® (NDA No. 204485)	PAR-VASO_0073585	PAR-VASO_0073629	

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DTX-046	12/1/2014	General Advice Letter from Y. Knight of the FDA to G. Vasquez of Par Sterile Products, LLC Enclosing Vasostrict™ (vasopressin injection) Prescribing Information (revised: 05/2014) (Reference ID: 3665841)	PAR-VASO_0014805	PAR-VASO_0014809	801, 802
DTX-047		JHP Pharmaceuticals, LLC Presentation: <i>Grandfathered Products: [Redacted] Pitressin®</i>	PAR-VASO_0204656	PAR-VASO_0204663	401, 402, 403
DTX-048	2/20/2018	Email from C. English to S. Vijayan et al. re RE: Vasostrict	PAR-VASO_0058400	PAR-VASO_0058402	401, 402, 403
DTX-049		Meeting Minutes: Compilation of Minutes for Specifications Committee Meetings dated January 10, 2012 through July 18, 2013	PAR-VASO_0120593	PAR-VASO_0120689	401, 402, 403, 801, 802, 901, 902, multiple separate documents
DTX-050	10/2012	Executed Conditional Offer of Employment Letter from S. Hinchey of JHP Pharmaceuticals, LLC to V. Kannan re the Position of Senior Formulations Development Scientist	PAR-VASO_0204767	PAR-VASO_0204771	401, 402, 403
DTX-051	1/2010	Pitressin® (vasopressin injection, USP) Synthetic Prescribing Information (revised: 01/2010)	PAR-VASO_0076133	PAR-VASO_0076134	
DTX-052	9/25/2012	Letter from G. Vasquez of JHP Pharmaceuticals, LLC to Dr. N. Stockbridge of the FDA re Original New Drug Application in eCTD Format; Pre NDA Meeting Package Pitressin® (vasopressin injection, USP), Synthetic	PAR-VASO_0072207	PAR-VASO_0072213	401, 402, 403, 801, 802
DTX-053		Par Pharmaceutical, Inc. Pharmaceutical Development Technical Report (No. FRD-14-001R): <i>Vasostrict® (vasopressin injection, USP) Justification of Time Out of Refrigeration</i>	PAR-VASO_0028307	PAR-VASO_0028352	
DTX-054	10/10/2014	Email from M. Kenney to V. Kannan re FW: vasostrict data	PAR-VASO_0088551	PAR-VASO_0088552	
DTX-055	7/17/2014	Email from P-A. Dardaine to S. Ahmed et al. re SA Rochester Slides - 07/18/14	PAR-VASO_0109802	PAR-VASO_0109802	
DTX-056	7/18/2014	Par Pharmaceutical, Inc. Presentation: <i>Rochester R&D: Par Sterile Products: Target Submissions 2014 - 2016: Project Management</i> 07/18/14	PAR-VASO_0109803	PAR-VASO_0109838	
DTX-057	7/31/2014	Email from P-A. Dardaine to S. Ahmed et al. re SA Rochester Slides - 08/01/14	PAR-VASO_0109842	PAR-VASO_0109842	
DTX-058	8/1/2014	Par Pharmaceutical, Inc. Presentation: <i>Rochester R&D: Par Sterile Products: Target Submissions 2014 - 2016: Project Management</i> 08/01/14	PAR-VASO_0109843	PAR-VASO_0109891	
DTX-059	8/14/2014	Email from P-A. Dardaine to S. Ahmed et al. re SA Rochester Slides - 08/15/14	PAR-VASO_0112061	PAR-VASO_0112061	
DTX-060	8/15/2014	Par Pharmaceutical, Inc. Presentation: <i>Rochester R&D: Par Sterile Products: Target Submissions 2014 - 2016: Project Management</i> 08/15/14	PAR-VASO_0112062	PAR-VASO_0112112	
DTX-061	9/24/2015	Email from P-A. Dardaine to S. Ahmed et al. re SA Rochester Slides - 09/25/15	PAR-VASO_0111627	PAR-VASO_0111627	
DTX-062	9/25/2015	Par Pharmaceutical, Inc. Presentation: <i>Rochester R&D: Par Sterile Products: Target Submissions 2015 - 2016: Project Management</i> 09/25/15	PAR-VASO_0111628	PAR-VASO_0111661	
DTX-063	10/8/2015	Email from P-A. Dardaine to S. Ahmed et al. re SA Rochester Slides - 10/09/15	PAR-VASO_0111539	PAR-VASO_0111539	

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DTX-064	10/9/2015	Par Pharmaceutical, Inc. Presentation: <i>Rochester R&D: Par Sterile Products: Target Submissions 2015 - 2016: Project Management</i> 10/09/15	PAR-VASO_0111540	PAR-VASO_0111573	401, 402, 403
DTX-065		Par Pharmaceutical, Inc. Product Development Technical Report (No. FRD-15-012): <i>Vasopressin, 20 Units/mL, pH 3.8 Acetate Buffer, Single Dose (Preservative Free) (Stock # 2002501)</i>	PAR-VASO_0093612	PAR-VASO_0093671	
DTX-066	3/22/2016	Email from V. Kannan to M. Kenney re RE: 4 week data	PAR-VASO_0034737	PAR-VASO_0034737	
DTX-067		Graph: <i>Rate of Change in Impurities (%/week) vs. Target pH</i> (25C Storage Condition)	PAR-VASO_0034748	PAR-VASO_0034748	
DTX-068		Spreadsheet: 4-Week Study Data Showcasing Rate of Change in Assay (%LC/week) and in Impurities (%/week) against Target pH	PAR-VASO_0034750	PAR-VASO_0034750	
DTX-069	1/22/2016	Declaration under 37 C.F.R. § 1.132 by Inventor Sunil Vandse, in re Application of: Matthew Kenney (U.S. Patent Appl. No. 14/717,882)	PAR-VASO-0002304	PAR-VASO-0002317	401, 402, 403
DTX-070	1/15/2015	Email from M. Kenney to S. Sanghvi et al. re vasopressin	PAR-VASO_0200879	PAR-VASO_0200879	
DTX-071		Par Pharmaceutical, Inc. Presentation: <i>Vasopressin Experimental Summary</i>	PAR-VASO_0200880	PAR-VASO_0200913	
DTX-072		Par Pharmaceutical NDA Module: 3.2.P.5.1 Specifications - Vasopressin® (NDA No. 204485)	PAR-VASO_0082707	PAR-VASO_0082708	401, 402, 403
DTX-073	8/15/2007	Agreement and General Release by and among King Pharmaceuticals, Inc. and Matthew Kenney, dated as of August 15, 2007	PAR-VASO_0204794	PAR-VASO_0204802	401, 402, 403
DTX-074	6/7/2017	Par Sterile Products, LLC Stability Tables: <i>Tabulated Stability Data through 23-Month Interval: Vasopressin (Vasopressin Injection, USP), 20 Units per mL, 1mL (New Formulation): Stock No. 2002501</i>	PAR-VASO_0042538	PAR-VASO_0042551	
DTX-075		Spreadsheet: 4-Week Study Data Showcasing Rate of Change in Assay (%LC/week) and in Impurities (%/week) against Target pH	PAR-VASO_0231067	PAR-VASO_0231067	
DTX-076		Electric Quilt File: <i>pH 2.5-3.5 Study 4 Weeks 3</i>	PAR-VASO_0034738	PAR-VASO_0034745	106, 1003, Vague
DTX-077		Graph: <i>Rate of Change in Assay (%LC/week) vs. Target pH</i> (25C Storage Condition)	PAR-VASO_0034746	PAR-VASO_0034746	
DTX-078		Graph: <i>Rate of Change in Assay (%LC/week) vs. Target pH</i> (40C Storage Condition)	PAR-VASO_0034747	PAR-VASO_0034747	
DTX-079		Graph: <i>Rate of Change in Impurities (%/week) vs. Target pH</i> (40C Storage Condition)	PAR-VASO_0034749	PAR-VASO_0034749	
DTX-080	6/10/2015	Email from M. Kenney to S. Sanghvi et al. re vaso lab batch 4 mo results	PAR-VASO_0215523	PAR-VASO_0215523	
DTX-081		Spreadsheet: 4-Month Vasopressin Batch Samples Assay and Impurities Data	PAR-VASO_0215524	PAR-VASO_0215524	
DTX-082		JHP Pharmaceuticals, LLC Laboratory Notebook (No. 71) of Matthew Kenney Regarding Pitressin (Issued: June 2014)	PAR-VASO_0059950	PAR-VASO_0060041	
DTX-083	2/9/2012	JHP Pharmaceuticals, LLC Quality Control Procedure Report (No. 20545): <i>Determination of Vasopressin and Impurities in Pitressin by Gradient HPLC</i> (Version: 3.0)	PAR-VASO_0073112	PAR-VASO_0073123	401, 402, 403
DTX-084		Spreadsheet: Pitressin® Inventory Shipment Data from July 28, 2008 through October 30, 2014	PAR-VASO_0248075	PAR-VASO_0248162	

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DTX-085		Spreadsheet: Pitressin® Inventory Shipment Data from October 9, 2007 through July 17, 2008	PAR-VASO_0248163	PAR-VASO_0248168	
DTX-086		Spreadsheet: Vasostrict® Inventory Shipment Data from November 12, 2014 through January 30, 2015	PAR-VASO_0248169	PAR-VASO_0248172	
DTX-087		Spreadsheet: Pitressin® Inventory Shipment Data from November 5, 2014 through November 6, 2014	PAR-VASO_0248364	PAR-VASO_0248364	
DTX-088	5/13/2015	Email from M. Kenney to S. Sanghvi & S. Vandse re vaso pH graphs	PAR-VASO_0032828	PAR-VASO_0032828	
DTX-089		Graph: Assay vs. Target pH 40C	PAR-VASO_0032829	PAR-VASO_0032829	
DTX-090		Graph: Assay vs. Target pH 25C	PAR-VASO_0032830	PAR-VASO_0032830	
DTX-091		Graph: Total Impurities vs. Target pH 40C	PAR-VASO_0032831	PAR-VASO_0032831	
DTX-092		Graph: Total Impurities vs. Target pH 25C	PAR-VASO_0032832	PAR-VASO_0032832	
DTX-093	10/23/2015	Email from N. Musaji to K. Mondejar et al. re RE: Stability Data for Shipping Temperature Complaints	PAR-VASO_0047264	PAR-VASO_0047269	401, 402, 403
DTX-094		JHP Pharmaceuticals NDA Module: 3.2.P.8.1 Stability Summary and Conclusion - Pitressin® (NDA No. 204485)	PAR-VASO_0073630	PAR-VASO_0073677	
DTX-095	1/24/2012	Email from M. Bergren to J. Brodowsky & J. Zebelian re RE: Specification and Spec rationale for Pitressin(2002132)	PAR-VASO_0052704	PAR-VASO_0052707	401, 402, 403
DTX-096		JHP Pharmaceuticals, LLC Product Specifications Release Report: SV 4200 Pitressin (Synthetic), 20 Units per 1 mL (Stock No. 2002132)	PAR-VASO_0052708	PAR-VASO_0052709	401, 402, 403
DTX-097	5/12/2016	Par Sterile Products, LLC Memorandum from S. Mikolajczak to V. Fremer re Pitressin/Vasostrict Annual Report	PAR-VASO_0047843	PAR-VASO_0047983	
DTX-098		Meeting Minutes: Vasostrict Launch Meeting dated July 2, 2014	PAR-VASO_0021007	PAR-VASO_0021011	401, 402, 403
DTX-099	10/21/2014	Email from M. Rennwald to J. Crist re FW: Pitressin stability	PAR-VASO_0053338	PAR-VASO_0053338	
DTX-100	2/27/2013	JHP Pharmaceuticals, LLC Product Development Technical Report (No. DEV-13-019): <i>Pitressin Registration Stability Studies: 9 Month Update</i>	PAR-VASO_0053339	PAR-VASO_0053398	
DTX-101	6/19/2012	JHP Pharmaceuticals, LLC Product Development Technical Report (No. DEV-12-031): <i>Three Month Interim Analysis of Registration Stability Studies for Pitressin</i>	PAR-VASO_0053399	PAR-VASO_0053449	
DTX-102	5/23/2014	Email from M. Rennwald to "Steve" re Pitressin No-overflow formula 5c stability data	PAR-VASO_0030282	PAR-VASO_0030282	
DTX-103		Spreadsheet: Pitressin No-Overflow Formula Stability Data (5C Storage Conditions)	PAR-VASO_0030283	PAR-VASO_0030294	
DTX-104	5/3/2004	Executed Offer of Employment Letter from S. Montalto of Par Pharmaceutical, Inc. to S. Sanghvi re the Position of Associate Director of the Formulations Department	PAR-VASO_0204772	PAR-VASO_0204786	401, 402, 403
DTX-105	7/24/2019	Plaintiffs' Objections and Responses to Defendant's Notice of Deposition Pursuant to Fed. R. Civ. P. 30(b)(6)			402, 403, 801, 802, AA
DTX-106		Par Pharmaceutical NDA Module: 3.2.P.1 Description and Composition - Vasostrict® (NDA No. 204485)	PAR-VASO_0082232	PAR-VASO_0082234	
DTX-107	5/21/2014	Email from M. Rutkowski to S. Richardson et al. re RE: Re-formulation	PAR-VASO_0015637	PAR-VASO_0015637	401, 402, 403

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EXHIBIT NO.	DATE	DESCRIPTION	BEG BATES NO.	END BATES NO.	OBJECTIONS
DTX-108	6/14/2012	JHP Pharmaceuticals, LLC Product Development Technical Report (No. DEV-12-029): <i>Supporting Stability Studies for Pitressin Injection</i>	PAR-VASO_0105305	PAR-VASO_0105401	
DTX-109	1/6/2014	Executed Offer of Employment Letter from S. Montalto of Par Pharmaceutical, Inc. to S. Vandse re the Position of Director of the Formulations Department	PAR-VASO_0204787	PAR-VASO_0204793	401, 402, 403
DTX-110	8/11/2015	Declaration under 37 C.F.R. § 1.132 by Inventor Sunil Vandse, in re Application of: Matthew Kenney (U.S. Patent Appl. No. 14/717,882)	PAR-VASO-0001039	PAR-VASO-0001046	401, 402, 403
DTX-111	11/14/2019	Opening Expert Report of Zlatan Coralic, Pharm.D., BCPS Regarding Infringement, and Exhibits Thereto			
DTX-112	1/20/2020	Reply Expert Report of Zlatan Coralic, Pharm.D., BCPS Regarding Infringement			
DTX-113	3/22/2019	Expert Declaration of Zlatan Coralic, Pharm.D., BCPS Regarding Claim Construction			
DTX-114	4/16/2019	Supplemental Expert Declaration of Zlatan Coralic, Pharm.D., BCPS Regarding Claim Construction			
DTX-115		Ashley Thompson Quan & Fanny Li, <i>Hyperinflation of Vasopressors (Vasopressin, Norepinephrine, Ephedrine, etc.)</i> , 31(4) J. Pharm. Prac. 399 (2018)			401, 402, 403, 801, 802, 901, 902
DTX-116		Aaron Hakim et al., <i>High Costs of FDA Approval for Formerly Unapproved Marketed Drugs</i> , 318(22) J. Am. Med. Ass'n 2181 (2017)			401, 402, 403, 801, 802, 901, 902
DTX-117		Zlatan Coralic (@ZEDPharm), Twitter (Feb. 27, 2016, 3:00 AM), https://twitter.com/zedpharm/status/703489975178768385			401, 402, 403, 801, 802, 901, 902
DTX-118	11/15/2019	Opening Expert Report of Lee E. Kirsch, Ph.D. Regarding Infringement of U.S. Patent Nos. 9,687,526, 9,744,209, and 9,750,785, and Exhibits Thereto			
DTX-119	12/22/2019	Rebuttal Expert Report of Lee E. Kirsch, Ph.D. Regarding Validity and Enforceability, and Exhibit Thereto			
DTX-120	1/20/2020	Reply Expert Report of Lee E. Kirsch, Ph.D. Regarding Infringement, and Exhibits Thereto			
DTX-121		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2017 Registration Batch, Batch SVA001 Inverted Position, DOM: 03Mar2017: Long Term (2° to 8°C) Stability Data, Stability Protocol PD SVA-01 Rev05</i>	EAGLEVAS0047274	EAGLEVAS0047277	801, 802
DTX-122	9/2019	VASOPRESSIN Injection Prescribing Information (revised: 09/2019)	EAGLEVAS0043566	EAGLEVAS0043568	801, 802
DTX-123		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2017 Registration Batch, Batch SVA001A Inverted Position, DOM: 03Mar2017: 25°C/60%RH Stability After 21 Months Storage at 2-8°C, Stability Protocol PD SVA-02 Rev02, Stability Start: 19Dec2018</i>	EAGLEVAS0047278	EAGLEVAS0047280	401, 402, 403, 801, 802

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DTX-124		Eagle Pharmaceuticals Inc. Stability Tables: Vasopressin Injection, USP 0.0377 mg/mL, 2017 Registration Batch, Batch SVA001A Upright Position, DOM: 03Mar2017: 25°C/60%RH Stability After 21 Months Storage at 2-8°C, Stability Protocol PD SVA-02 Rev02, Stability Start: 19Dec2018	EAGLEVAS0047281	EAGLEVAS0047283	401, 402, 403, 801, 802
DTX-125		Eagle Pharmaceuticals Inc. Stability Tables: Vasopressin Injection, USP 0.0377 mg/mL, 2017 Registration Batch, Batch SVA002 Inverted Position, DOM: 07Mar2017: Long Term (2° to 8°C) Stability Data, Stability Protocol PD SVA-01 Rev05	EAGLEVAS0047284	EAGLEVAS0047287	801, 802
DTX-126		Eagle Pharmaceuticals Inc. Stability Tables: Vasopressin Injection, USP 0.0377 mg/mL, 2017 Registration Batch, Batch SVA002A Inverted Position, DOM: 07Mar2017: 25°C/60%RH Stability After 21 Months Storage at 2-8°C, Stability Protocol PD SVA-02 Rev02, Stability Start: 19Dec2018	EAGLEVAS0047288	EAGLEVAS0047290	401, 402, 403, 801, 802
DTX-127		Eagle Pharmaceuticals Inc. Stability Tables: Vasopressin Injection, USP 0.0377 mg/mL, 2017 Registration Batch, Batch SVA002A Upright Position, DOM: 07Mar2017: 25°C/60%RH Stability After 21 Months Storage at 2-8°C, Stability Protocol PD SVA-02 Rev02, Stability Start: 19Dec2018	EAGLEVAS0047291	EAGLEVAS0047293	401, 402, 403, 801, 802
DTX-128		Eagle Pharmaceuticals Inc. Stability Tables: Vasopressin Injection, USP 0.0377 mg/mL, 2017 Registration Batch, Batch SVA003 Inverted Position, DOM: 10Mar2017: Long Term (2° to 8°C) Stability Data, Stability Protocol PD SVA-01 Rev05	EAGLEVAS0047294	EAGLEVAS0047297	801, 802
DTX-129		Eagle Pharmaceuticals Inc. Stability Tables: Vasopressin Injection, USP 0.0377 mg/mL, 2017 Registration Batch, Batch SVA003A Inverted Position, DOM: 10Mar2017: 25°C/60%RH Stability After 21 Months Storage at 2-8°C, Stability Protocol PD SVA-02 Rev02, Stability Start: 19Dec2018	EAGLEVAS0047298	EAGLEVAS0047300	401, 402, 403, 801, 802
DTX-130		Eagle Pharmaceuticals Inc. Stability Tables: Vasopressin Injection, USP 0.0377 mg/mL, 2017 Registration Batch, Batch SVA003A Upright Position, DOM: 10Mar2017: 25°C/60%RH Stability After 21 Months Storage at 2-8°C, Stability Protocol PD SVA-02 Rev02, Stability Start: 19Dec2018	EAGLEVAS0047301	EAGLEVAS0047303	401, 402, 403, 801, 802
DTX-131		Eagle Pharmaceuticals ANDA Module: 1.12.12 Comparison of Generic Drug and RLD - Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0000076	EAGLEVAS0000077	801, 802
DTX-132	5/7/2015	Supplemental NDA Approval Letter from Dr. W. Wilson-Lee of the FDA to G. Vasquez of Par Sterile Products, LLC Enclosing Vasostrict™ (vasopressin injection) Prescribing Information (revised: 03/2015) and Package Labeling	PAR-VASO_0014782	PAR-VASO_0014787	801, 802
DTX-133	9/11/2019	Major Complete Response Amendment Letter from M. Stern of Eagle Pharmaceuticals Inc. to the FDA re ANDA No. 211538	EAGLEVAS0043614	EAGLEVAS0043663	801, 802

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EXHIBIT NO.	DATE	DESCRIPTION	BEG BATES NO.	END BATES NO.	OBJECTIONS
DTX-134	3/24/2017	OSO BioPharmaceuticals Manufacturing, LLC Certificate of Analysis: Vasopressin, 20 units/vial (0.0377 mg/mL) (Lot No. SVA001)	EAGLEVAS0002277	EAGLEVAS0002277	801, 802
DTX-135		U.S. Pharmacopeia, <i>Vasopressin Injection</i> , in 3 The National Formulary 3849 (2009)	EAGLEVAS0058037	EAGLEVAS0058040	
DTX-136	6/2009	Vasopressin Injection, USP (Synthetic) Prescribing Information (revised: 06/2009) (Manufacturer: Pharmaceutical Partners of Canada Inc.)	EAGLEVAS0014005	EAGLEVAS0014005	801, 802
DTX-137	5/14/2019	Supplemental NDA Approval Letter from M. Southworth of the FDA to C. English of Par Sterile Products, LLC Enclosing VASOSTRICT® (vasopressin injection) Prescribing Information (revised: 05/2019) (Reference ID: 4432979)	PAR-VASO_0230785	PAR-VASO_0230795	401, 402, 403, 801, 802
DTX-138	11/4/2019	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Conditions: 5C Inverted, 5C Upright) (Lot Nos. SVA007.5I, SVA007.5U)	AMRIVAS0117046	AMRIVAS0117049	401, 402, 403, 801, 802
DTX-139	11/4/2019	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Conditions: 25C/60%RH Inverted, 25C/60%RH Upright) (Lot Nos. SVA007.25I, SVA007.25U)	AMRIVAS0117042	AMRIVAS0117045	401, 402, 403, 801, 802
DTX-140	11/4/2019	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Conditions: 5C Inverted, 5C Upright) (Lot Nos. SVA008.5I, SVA008.5U)	AMRIVAS0117054	AMRIVAS0117057	401, 402, 403, 801, 802
DTX-141	11/4/2019	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Conditions: 25C/60%RH Inverted, 25C/60%RH Upright) (Lot Nos. SVA008.25I, SVA008.25U)	AMRIVAS0117050	AMRIVAS0117053	401, 402, 403, 801, 802
DTX-142	12/11/2019	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Conditions: 5C Inverted, 5C Upright) (Lot Nos. SVA009.5I, SVA009.5U)	AMRIVAS0117062	AMRIVAS0117065	401, 402, 403, 801, 802
DTX-143	12/11/2019	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Conditions: 25C/60%RH Inverted, 25C/60%RH Upright) (Lot Nos. SVA009.25I, SVA009.25U)	AMRIVAS0117058	AMRIVAS0117061	401, 402, 403, 801, 802
DTX-144	4/26/1999	Lithuanian Patent No. LT 4487 B to Gendrolis et al.	PAR-VASO_0233012	PAR-VASO_0233022	401, 402, 403, 701, 702, 801, 802, PMIL, 901, 902
DTX-145	11/14/2019	Opening Expert Report of Robert Minkin, FACHE, and Exhibits Thereto			
DTX-146	1/20/2020	Reply Expert Report of Robert Minkin, FACHE			
DTX-147	9/6/2019	Email from S. Gagliardi of Dechert LLP to C. Citro of Kirkland & Ellis LLP re Plaintiffs' Supplemental Objections and Responses to Defendants' Interrogatories and Plaintiffs' Validity Contentions			402, 403, 801, 802, AA
DTX-148	9/27/2019	Plaintiffs' Objections and Responses to Eagle Pharmaceuticals Inc.'s Second Set of Requests for Admissions (Nos. 74-276) to Par Pharmaceutical			401, 402, 403, 801, 802, AA, Legal
DTX-149	10/16/2019	Plaintiffs' Final Infringement Contentions, and Exhibits Thereto			401, 402, 403, 801, 802, AA, Legal
DTX-150		Mettler-Toledo AG, pH Theory Guide: A Guide to pH Measurement: Theory and Practice of pH Application (2013)	EAGLEVAS0014434	EAGLEVAS0014537	801, 802

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DTX-151	12/2016	NDA Approval Letter from Dr. R. Raghavachari of the FDA to C. English of Par Sterile Products, LLC Enclosing VASOSTRICT® (vasopressin injection) Prescribing Information (revised: 12/2016)	PAR-VASO_0014439	PAR-VASO_0014442	801, 802
DTX-152	5/3/2019	The Parties' Joint Claim Construction Brief, and Attachment Thereto (D.I. 61)			401, 402, 403, 801, 802, AA, Legal
DTX-153	4/17/2019	Declaration of Lee E. Kirsch, Ph.D. Regarding Claim Construction, and Exhibit Thereto, Submitted as Exhibit 32 to the Parties' Joint Claim Construction Appendix (D.I. 62)			
DTX-154	1/17/2018	Albany Molecular Research Inc. Standard Operating Procedure Report (No. STA-EPX-0119): <i>Vasopressin Injection, USP, End Product Test Procedure</i> (Revision: 03)	EAGLEVAS0001349	EAGLEVAS0001380	801, 802
DTX-155	8/2/2019	Albany Molecular Research Inc. Standard Operating Procedure Report (No. STA-EPX-0119): <i>Vasopressin Injection, USP, End Product Test Procedure</i> (Revision: 06)	EAGLEVAS0046178	EAGLEVAS0046210	801, 802
DTX-156		G. Mattock & G. Ross Taylor, <i>Buffer Solutions, in</i> pH Measurement and Titration 39 (1961)	EAGLEVAS0014374	EAGLEVAS0014395	801, 802
DTX-157	10/28/2019	Plaintiffs' Claim Construction Response Brief, <i>Par Pharm., Inc. v. Sandoz Inc.</i> , No. 3:18-cv-14895-BRM-DEA (D.N.J. Oct. 28, 2019), ECF No. 63			401, 402, 403, 801, 802, AA, Legal
DTX-158	4/2009	Letter from Dr. R. Whitfield of JHP Pharmaceuticals, LLC to Dr. L. Callahan Enclosing JHP Pharmaceuticals, LLC Research Report (No. 703-00159): <i>Analytical Method Validation Report for the Determination of Vasopressin and Impurities in Pitressin by Gradient HPLC</i>	PAR-VASO_0108652	PAR-VASO_0108699	401, 402, 403, 801, 802, 901, 902
DTX-159	1/30/2015	Original U.S. Patent Appl. No. 14/610,499	EAGLEVAS0057997	EAGLEVAS0058036	
DTX-160		U.S. Pharmacopeia, <791> pH, in The National Formulary 343 (2012)	EAGLEVAS0058041	EAGLEVAS0058042	
DTX-161		U.S. Pharmacopeia, <1225> Validation of Compendial Procedures, in The National Formulary 1 (2013)	EAGLEVAS0058043	EAGLEVAS0058047	401, 402, 403
DTX-162	11/2019	Curriculum Vitae of Mansoor M. Amiji, Ph.D., R.Ph.			401, 402, 403, 801, 802
DTX-162A	12/2020	Updated Curriculum Vitae of Mansoor M. Amiji, Ph.D., R.Ph.			
DTX-163	11/14/2019	List of Materials Considered for Opening Expert Report of Dr. Mansoor M. Amiji, Ph.D., R.Ph. Concerning Invalidity of U.S. Patent Nos. 9,687,526; 9,744,209; and 9,750,785			801, 802
DTX-164	8/26/2019	Plaintiffs' Objections and Responses to Eagle Pharmaceuticals Inc.'s First Set of Requests for Admissions (Nos. 1-73) to Par Pharmaceutical			401, 402, 403, 801, 802, AA, Legal
DTX-165	10/22/2019	Plaintiffs' Fourth Supplemental Objections and Responses to Eagle Pharmaceuticals Inc.'s Interrogatories (Nos. 13, 23)			401, 402, 403, 801, 802, AA, Legal
DTX-166	9/19/2011	U.S. Food & Drug Admin., <i>Guidance for FDA Staff and Industry: Marketed Unapproved Drugs - Compliance Policy Guide</i> (Sept. 19, 2011)			401, 402, 403, 801, 802, 901, 902
DTX-167	12/31/2011	Loyd V. Allen, Jr., <i>pH and Solubility, Stability, and Absorption, Part II</i> , 1(8) Sci. & Tech. for the Hosp. Pharmacist (Dec. 31, 2011)	EAGLEVAS0055820	EAGLEVAS0055823	801, 802

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EXHIBIT NO.	DATE	DESCRIPTION	BEG BATES NO.	END BATES NO.	OBJECTIONS
DTX-168	12/2/2013	Luitpold Pharmaceuticals, Inc. Finished Product Specifications and Monograph Report: Vasopressin Injection, USP (Version: 11.0)	AR3-VASO-0000001	AR3-VASO-0000008	801, 802, 901, 902
DTX-169		Spreadsheet: Vasopressin Inventory Shipment Data	AR3-VASO-0000009	AR3-VASO-0000009	801, 802, 901, 902
DTX-170	4/9/2019	American Regent, Inc. Stability Tables: Vasopressin Injection, USP, 20 units/mL (Storage Condition: 25C +/- 2C Inverted) (Lot No. 6045.RI)	AR3-VASO-0000010	AR3-VASO-0000011	801, 802, 901, 902
DTX-171	1/15/1996	American Regent, Inc. Master Formula Report: Vasopressin Injection, USP, 20 units/mL (Lot. No. 6045)	AR3-VASO-0000012	AR3-VASO-0000017	801, 802, 901, 902
DTX-172		Luitpold Pharmaceuticals, Inc. Method Development Report: Vasopressin Injection, USP: <i>HPLC Chromatographic Purity Method</i>	AR3-VASO-0000018	AR3-VASO-0000022	801, 802, 901, 902
DTX-173		Mingda Bi & Jagdish Singh, <i>Effect of Buffer pH, Buffer Concentration and Skin with or without Enzyme Inhibitors on the Stability of [Arg⁸]-Vasopressin</i> , 197 Int'l. J. Pharm. 87 (2000)	PAR-VASO_0030301	PAR-VASO_0030307	
DTX-174		Eagle Pharmaceuticals ANDA Module: 2.3.P Drug Product - Supplement: Question-Based Review for Drug Product - Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0043670	EAGLEVAS0043790	801, 802
DTX-175		Andrea Hawe et al., <i>Towards Heat-Stable Oxytocin Formulations: Analysis of Degradation Kinetics and Identification of Degradation Products</i> , 26(7) Pharm. Res. 1679 (2009)	EAGLEVAS0013885	EAGLEVAS0013894	401, 402, 403, 801, 802
DTX-176		<i>Limiting Steps in Uncatalyzed and H⁺ - and HO⁻ - Catalyzed Hydrolysis of the Amide Bond</i> , 41 Int'l J. Chem. Kinetics 599 (2009)	EAGLEVAS0057896	EAGLEVAS0057908	801, 802
DTX-177		Shouping Liu et al., <i>Effect of Structural Parameters of Peptides on Dimer Formation and Highly Oxidized Side Products in the Oxidation of Thiols of Linear Analogues of Human β-Defensin 3 by DMSO</i> , 15 J. Peptide Sci. 95 (2009)	EAGLEVAS0057909	EAGLEVAS0057920	801, 802
DTX-178	10/2012	Pitressin® (vasopressin injection, USP) Synthetic Prescribing Information (revised: 10/2012)	PAR-VASO_0219794	PAR-VASO_0219795	
DTX-179	6/7/2012	JHP Pharmaceuticals, LLC Specifications Committee Presentation: <i>Pitressin Product Specifications (Stock 2002132, Reduced Overage)</i> (Presenter: Mike Bergren)	PAR-VASO_0029982	PAR-VASO_0030009	401, 402, 403
DTX-180		JHP Pharmaceuticals NDA Module: 3.2.P.1 Description and Composition of the Drug Product - Pitressin® (NDA No. 204485)	PAR-VASO_0072719	PAR-VASO_0072720	
DTX-181	3/8/2013	JHP Pharmaceuticals, LLC Master Batch Record: SV 4200 Pitressin (Synthetic) USP, 20 Units per 1 mL (Stock No. 2000179) (Revision Code: 025)	PAR-VASO_0078041	PAR-VASO_0078161	
DTX-182		JHP Pharmaceuticals, LLC Formulations Comparison Report: Comparison of Vasopressin Formulations from APP and American Regent against the Vasopressin Formulation of JHP Pharmaceuticals	PAR-VASO_0089788	PAR-VASO_0089791	
DTX-183	6/7/2002	King Pharmaceuticals, Inc. Memorandum from L. Stiles to Rx 48783 Batch Record re Product Validation Addendum Testing	PAR-VASO_0094514	PAR-VASO_0094515	801, 802
DTX-184		Spreadsheet: Pitressin® Pressor Activity, Chlorobutanol, and pH Specifications Normal Stability Data and Corresponding Graphs	PAR-VASO_0094977	PAR-VASO_0094977	401, 402, 403

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EXHIBIT NO.	DATE	DESCRIPTION	BEG BATES NO.	END BATES NO.	OBJECTIONS
DTX-185	1/18/2005	King Pharmaceuticals, Inc. Memorandum from K. Jones to Pitressin File re pH Matrix for SV 4200 Pitressin (Synthetic) USP, 20 Units per 1 mL	PAR-VASO_0095005	PAR-VASO_0095005	801, 802
DTX-186		Spreadsheet: <i>SV 4200 Pitressin Ampoule Validation Data to Date</i>	PAR-VASO_0095102	PAR-VASO_0095102	401, 402, 403
DTX-187	3/4/2008	JHP Pharmaceuticals, LLC Memorandum from K. Mondejar to B. Boesch re Regression Analysis of Pitressin Synthetic, 20 Units per 1 mL with Teflon 2 Stoppers	PAR-VASO_0108554	PAR-VASO_0108570	801, 802
DTX-188	5/26/2009	JHP Pharmaceuticals, LLC Memorandum from D. Battisti to B. Boesch et al. re Analytical Progress: Pitressin Biweekly Meeting	PAR-VASO_0108640	PAR-VASO_0108651	801, 802
DTX-189	6/19/2008	JHP Pharmaceuticals Inc. Stability Tables: SV 4200 Pitressin (Synthetic) USP, 20 Units/mL (Storage Condition: 25C/60% RH) (Stock No. 2000179)	PAR-VASO_0108703	PAR-VASO_0108710	
DTX-190	6/19/2008	JHP Pharmaceuticals Inc. Stability Tables: SV 4200 Pitressin (Synthetic) USP, 20 Units/mL (Storage Condition: 25C/60% RH) (Stock Nos. 2000179, 4200X955) ; Pitressin Synthetic Amp 4200, 20 Units/mL (N. I. S.) (Storage Conditions: 25C/60% RH, 25C) (Stock Nos. 4200X913, 4200X912)	PAR-VASO_0108711	PAR-VASO_0108722	401, 402, 403
DTX-191	1/14/2008	JHP Pharmaceuticals Inc. Stability Tables: Pitressin Synthetic Amp 4200, 20 Units/mL (N. I. S.) (Storage Condition: 25C) (Stock Nos. 4200A913, 4200A912, 4200X913)	PAR-VASO_0108983	PAR-VASO_0108985	401, 402, 403
DTX-192	1/15/2008	JHP Pharmaceuticals Inc. Stability Tables: Pitressin Synthetic Amp 4200, 20 Units/mL (N. I. S.) (Storage Condition: 25C) (Stock No. 4200X912)	PAR-VASO_0108986	PAR-VASO_0108988	401, 402, 403
DTX-193		Spreadsheet: <i>SV 4200 Pitressin Ampoule Validation Data to Date</i>	PAR-VASO_0109017	PAR-VASO_0109020	401, 402, 403
DTX-194		Parkedale Pharmaceuticals Product Validation Addendum: Pitressin (Synthetic) USP Bulk Solution, 20 Units per mL (Stock No. AMP 4200: 4200X912)	PAR-VASO_0201451	PAR-VASO_0201454	401, 402, 403, 801, 802
DTX-195		Par Pharmaceutical Inc. Laboratory Notebook (No. 1281) of Alexandra Draghici Regarding Vasostrict® (Issued: Feb. 3, 2015)	PAR-VASO_0246222	PAR-VASO_0246429	
DTX-196		Par Pharmaceutical Inc. Laboratory Notebook (No. 1283) of Alexandra Draghici Regarding Vasostrict® (Issued: Mar. 26, 2015)	PAR-VASO_0246430	PAR-VASO_0246652	
DTX-197		Arthur B. Robinson & James W. Scotchler, <i>Sequence Dependent Deamidation Rates for Model Peptides of Histone IV</i> , 6 Int'l J. Peptide Protein Res. 279 (1974)	EAGLEVAS0057921	EAGLEVAS0057924	401, 402, 403, 801, 802
DTX-198		Robert M. Smith & David E. Hansen, <i>The pH-Rate Profile for the Hydrolysis of a Peptide Bond</i> , 120 J. Am. Chem. Soc'y 8910 (1998)	EAGLEVAS0057925	EAGLEVAS0057928	801, 802
DTX-199		John R. Taylor, <i>An Introduction to Error Analysis: The Study of Uncertainties in Physical Measurements</i> (2d ed. 1997)	EAGLEVAS0057929	EAGLEVAS0057991	801, 802
DTX-200		O. A. G. J. van der Houwen et al., <i>Systematic Interpretation of pH-Degradation Profiles. A Critical Review</i> , 155 Int'l J. Pharm. 137 (1997)	EAGLEVAS0058048	EAGLEVAS0058063	801, 802
DTX-201	4/2013	W.H.O. International Standard: ARGININE VASOPRESSIN (AVP) Instructions for Use (revised: 04/2013) (Version: 6.0)	EAGLEVAS0014037	EAGLEVAS0014038	801, 802

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DTX-202		Luwei Zhao & Samuel H. Yalkowsky, <i>Stabilization of Eptifibatide by Cosolvents</i> , 218 Int'l J. Pharm. 43 (2001)	EAGLEVAS0058338	EAGLEVAS0058351	801, 802
DTX-203	5/24/2019	Curriculum Vitae of Leonard J. Chyall, Ph.D.			401, 402, 403, 801, 802
DTX-203A	10/22/2020	Updated Curriculum Vitae of Leonard J. Chyall, Ph.D.			
DTX-204	11/15/2019	List of Materials Considered for Opening Expert Report of Leonard J. Chyall, Ph.D.			801, 802
DTX-205	3/22/2019	Declaration of Zlatan Coralic, Pharm.D., BCPS Regarding Claim Construction, and Exhibit Thereto, Submitted as Exhibit 20 to the Parties' Joint Claim Construction Appendix (D.I. 62)			
DTX-206		Betty L. Gahart & Adrienne R. Nazareno, <i>Vasopressin Injection</i> , in <i>Intravenous Medications</i> 1167 (29th ed. 2013)	EAGLEVAS0051875	EAGLEVAS0051883	801, 802
DTX-207	12/3/2018	Plaintiffs' Objections and Responses to Eagle Pharmaceuticals Inc.'s First Set of Interrogatories (Nos. 1-13)			401, 402, 403, 801, 802, AA, Legal
DTX-208		Am. Hosp. Formulary Serv., <i>Vasopressin</i> , in <i>AHFS Drug Information</i> 3261 (2011)	EAGLEVAS0052180	EAGLEVAS0052184	801, 802
DTX-209		Jeffrey A. Alten et al., <i>Early Initiation of Arginine Vasopressin Infusion in Neonates after Complex Cardiac Surgery</i> , 13(3) <i>Pediatric Critical Care Med.</i> 300 (2012)	EAGLEVAS0034748	EAGLEVAS0034752	801, 802
DTX-210		Michael Argenziano et al., <i>A Prospective Randomized Trial of Arginine Vasopressin in the Treatment of Vasodilatory Shock after Left Ventricular Assist Device Placement</i> , 96(suppl II) <i>Circulation</i> II-286 (1997)	EAGLEVAS0013664	EAGLEVAS0013668	801, 802
DTX-211		Michael Argenziano et al., <i>Management of Vasodilatory Shock after Cardiac Surgery: Identification of Predisposing Factors and Use of a Novel Pressor Agent</i> , 116 <i>J. Thoracic Cardiovascular Surgery</i> 973 (1998)	EAGLEVAS0036637	EAGLEVAS0036644	801, 802
DTX-212	2/2013	R. Isaac, <i>VASOPRESSIN 10 Units in 50 mL IV INFUSION for Vasopressor Effect</i> , in <i>Birmingham Children's Hospital Injectable Medicine Guide</i> (Feb. 2013)	EAGLEVAS0013837	EAGLEVAS0013838	801, 802
DTX-213		R. P. Dellinger et al., <i>Surviving Sepsis Campaign: International Guidelines for Management of Severe Sepsis and Septic Shock</i> , 2012, 39 <i>Intensive Care Med.</i> 165 (2013)	EAGLEVAS0055873	EAGLEVAS0055936	801, 802
DTX-214		M. W. Dünser et al., <i>Cardiac Performance during Vasopressin Infusion in Postcardiotomy Shock</i> , 28 <i>Intensive Care Med.</i> 746 (2002)	EAGLEVAS0013857	EAGLEVAS0013862	801, 802
DTX-215		Martin W. Dünser et al., <i>Arginine Vasopressin in Advanced Vasodilatory Shock: A Prospective, Randomized, Controlled Study</i> , 107 <i>Circulation</i> 2313 (2003)	EAGLEVAS0033530	EAGLEVAS0033536	801, 802
DTX-216		Suruchi Hasija et al., <i>Prophylactic Vasopressin in Patients Receiving the Angiotensin-Converting Enzyme Inhibitor Ramipril Undergoing Coronary Artery Bypass Graft Surgery</i> , 24(2) <i>J. Cardiothoracic Vascular Anesthesia</i> 230 (2010)	EAGLEVAS0037890	EAGLEVAS0037898	801, 802

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DTX-217		Cheryl L. Holmes et al., <i>The Effects of Vasopressin on Hemodynamics and Renal Function in Severe Septic Shock: A Case Series</i> , 27 Intensive Care Med. 1416 (2001)	EAGLEVAS0038761	EAGLEVAS0038766	801, 802
DTX-218		François Lauzier et al., <i>Vasopressin or Norepinephrine in Early Hyperdynamic Septic Shock: A Randomized Clinical Trial</i> , 32 Intensive Care Med. 1782 (2006)	EAGLEVAS0039509	EAGLEVAS0039516	801, 802
DTX-219		Evelyn Lechner et al., <i>Arginine-Vasopressin in Neonates with Vasodilatory Shock after Cardiopulmonary Bypass</i> , 166 Eur. J. Pediatrics 1221 (2007)	EAGLEVAS0013931	EAGLEVAS0013937	801, 802
DTX-220	1/2014	P. Nekić & S. Shunker, <i>Vasopressin</i> , in <i>Liverpool Hospital ICU Guideline: Pharmacology</i> (Jan. 2014)	EAGLEVAS0035772	EAGLEVAS0035775	801, 802
DTX-221		Mary Beth Malay et al., <i>Low-Dose Vasopressin in the Treatment of Vasodilatory Septic Shock</i> , 47(4) J. Trauma: Injury, Infection, & Critical Care 699 (1999)	PAR-VASO_0108180	PAR-VASO_0108186	801, 802
DTX-222		David L. S. Morales et al., <i>Arginine Vasopressin in the Treatment of 50 Patients with Postcardiotomy Vasodilatory Shock</i> , 69 Ann. Thoracic Surgery 102 (2000)	EAGLEVAS0033571	EAGLEVAS0033575	801, 802
DTX-223		David L. S. Morales et al., <i>A Double-Blind Randomized Trial: Prophylactic Vasopressin Reduces Hypotension after Cardiopulmonary Bypass</i> , 75 Ann. Thoracic Surgery 926 (2003)	EAGLEVAS0033096	EAGLEVAS0033100	801, 802
DTX-224	3/2016	NDA Approval Letter from Dr. R. Raghavachari of the FDA to C. English of Par Sterile Products, LLC Enclosing VASOSTRICT® (vasopressin injection) Prescribing Information (revised: 11/2015) and Package Labeling	PAR-VASO_0014542	PAR-VASO_0014547	801, 802
DTX-225		Marilee D. Obritsch et al., <i>Effects of Continuous Vasopressin Infusion in Patients with Septic Shock</i> , 38 Ann. Pharmacotherapy 1117 (2004)	EAGLEVAS0013987	EAGLEVAS0013992	801, 802
DTX-226		Georgios Papadopoulos et al., <i>Perioperative Infusion of Low-Dose of Vasopressin for Prevention and Management of Vasodilatory Vasoplegic Syndrome in Patients Undergoing Coronary Artery Bypass Grafting - A Double-Blind Randomized Study</i> , 5(17) J. Cardiothoracic Surgery (2010)	EAGLEVAS0037343	EAGLEVAS0037354	801, 802
DTX-227	4/1/2013	Letter from G. Vasquez of JHP Pharmaceuticals, LLC to Dr. N. Stockbridge of the FDA re Pitressin® (vasopressin injection, USP), Synthetic NDA #204485, S/N 0008; Response to Information Request Received December 7, 2012	PAR-VASO_0076965	PAR-VASO_0076967	801, 802
DTX-228	5/3/2013	Letter from G. Vasquez of JHP Pharmaceuticals, LLC to Dr. N. Stockbridge of the FDA re Pitressin® (vasopressin injection, USP), Synthetic NDA #204485, S/N 0011; Response to Clinical Pharmacology Information Requests Received April 22, 2013 & Completed Development Studies with Dextrose	PAR-VASO_0077264	PAR-VASO_0077267	801, 802
DTX-229	3/26/2013	JHP Pharmaceuticals, LLC Product Development Technical Report (No. DEV-13-022): <i>Stability of Admixtures of Pitressin with D5W</i>	PAR-VASO_0078911	PAR-VASO_0078931	

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EXHIBIT NO.	DATE	DESCRIPTION	BEG BATES NO.	END BATES NO.	OBJECTIONS
DTX-230		Bhavesh M. Patel et al., <i>Beneficial Effects of Short-Term Vasopressin Infusion during Severe Septic Shock</i> , 96(3) <i>Anesthesiology</i> 576 (2002)	EAGLEVAS0013993	EAGLEVAS0013999	801, 802
DTX-231		Erika Berman Rosenzweig et al., <i>Intravenous Arginine-Vasopressin in Children with Vasodilatory Shock after Cardiac Surgery</i> , 100(suppl II) <i>Circulation</i> II-182 (1999)	EAGLEVAS0036273	EAGLEVAS0036278	801, 802
DTX-232		James A. Russell et al., <i>Vasopressin versus Norepinephrine Infusion in Patients with Septic Shock</i> , 358(9) <i>New Eng. J. Med.</i> 877 (2008)	EAGLEVAS0014006	EAGLEVAS0014016	801, 802
DTX-233		Supplementary Appendix to: James A. Russell et al., <i>Vasopressin versus Norepinephrine Infusion in Patients with Septic Shock</i> , 358(9) <i>New Eng. J. Med.</i> 877 (2008)	PAR-VASO_0108219	PAR-VASO_0108236	801, 802
DTX-234	9/2014	Vasostriect™ (vasopressin injection) Prescribing Information (revised: 09/2014) (Reference ID: 3665822)	EAGLEVAS0036325	EAGLEVAS0036328	
DTX-235		Qinghua Sun et al., <i>Low-Dose Vasopressin in the Treatment of Septic Shock in Sheep</i> , 168 <i>Am. J. Respiratory & Critical Care Med.</i> 481 (2003)	EAGLEVAS0014017	EAGLEVAS0014022	801, 802
DTX-236	7/22/2019	Paul Tonog & Anand D. Lakhkar, <i>Normal Saline</i> , NCBI Bookshelf (July 22, 2019), https://www.ncbi.nlm.nih.gov/books/NBK545210/?report=printable	EAGLEVAS0057992	EAGLEVAS0057996	801, 802
DTX-237		Christian Torgersen et al., <i>Comparing Two Different Arginine Vasopressin Doses in Advanced Vasodilatory Shock: A Randomized, Controlled, Open-Trial Label</i> , 36 <i>Intensive Care Med.</i> 57 (2010)	EAGLEVAS0034376	EAGLEVAS0034384	801, 802
DTX-238		Tanja A. Treschan & Jürgen Peters, <i>The Vasopressin System: Physiology and Clinical Strategies</i> , 105(3) <i>Anesthesiology</i> 599 (2006)	EAGLEVAS0014023	EAGLEVAS0014036	801, 802
DTX-239		Sarah Catherine Walpole et al., <i>The Weight of Nations: An Estimation of Adult Human Biomass</i> , 12(439) <i>BMC Pub. Health</i> (2012)	EAGLEVAS0014538	EAGLEVAS0014543	401, 402, 403, 801, 802
DTX-240	1/22/2009	WIPO Int'l Pub. No. WO 2009/009907 to Russell et al.	EAGLEVAS0043158	EAGLEVAS0043215	801, 802
DTX-241		Curriculum Vitae of Carmen A. Cross, M.D., F.A.C.E.P.			401, 402, 403, 801, 802
DTX-242	11/14/2019	List of Materials Considered for Opening Expert Report of Carmen A. Cross, M.D.			801, 802
DTX-243	7/30/2019	Plaintiffs' Objections and Responses to Eagle Pharmaceuticals Inc.'s Second Set of Interrogatories (Nos. 14-22)			401, 402, 403, 801, 802, AA, Legal
DTX-244	8/23/2019	Plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC's Response to Defendant Eagle Pharmaceuticals Inc.'s Invalidity Contentions			401, 402, 403, 801, 802, AA, Legal
DTX-245	9/6/2019	Plaintiffs' Supplemental Objections and Responses to Eagle Pharmaceuticals Inc.'s Second and Third Sets of Interrogatories (Nos. 14, 17-19, 23-24)			401, 402, 403, 801, 802, AA, Legal
DTX-246	5/2011	Vasopressin Injection, USP (Synthetic) Prescribing Information (revised: 05/2011) (Manufacturer: American Regent, Inc.)	PAR-VASO-0002051	PAR-VASO-0002058	801, 802

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EXHIBIT NO.	DATE	DESCRIPTION	BEG BATES NO.	END BATES NO.	OBJECTIONS
DTX-247		Byeong S. Chang & Susan Hershenson, <i>Practical Approaches to Protein Formulation Development</i> , in Rational Design of Stable Protein Formulations 1 (J.F. Carpenter et al. eds., 2002)	PAR-VASO-0005826	PAR-VASO-0005850	801, 802
DTX-248		Mingda Bi & Jagdish Singh, <i>HPLC Method for Quantification of Arginine Containing Vasopressin</i> , 22(4) J. Liquid Chromatography & Related Techs. 551 (1999)	EAGLEVAS0013839	EAGLEVAS0013850	801, 802
DTX-249	10/2012	Pitressin® (vasopressin injection, USP) Synthetic Prescribing Information (revised: 10/2012) (Repackaging Manufacturer: Cardinal Health)	EAGLEVAS0013851	EAGLEVAS0013856	801, 802
DTX-250	9/11/2014	The Joint Commission Webinar Presentation: <i>The Misuse of Vials: A Follow-Up to the Sentinel Event Alert</i> (Presenters: Ana McKee et al.)	EAGLEVAS0013895	EAGLEVAS0013930	801, 802
DTX-251		Jadwiga Dudkiewicz-Wilczyńska et al., <i>Determination of the Content of Desmopressin in Pharmaceutical Preparations by HPLC and Validation of the Method</i> , 59(3) Acta Poloniae Pharmaceutica 163 (2002)	EAGLEVAS0014039	EAGLEVAS0014044	801, 802
DTX-252		Masashi Yanagisawa et al., <i>A Novel Potent Vasoconstrictor Peptide Produced by Vascular Endothelial Cells</i> , 332 Nature 411 (1988)	EAGLEVAS0014045	EAGLEVAS0014050	801, 802
DTX-253	3/27/2014	FDA Summary Review of Proposed Drug Product, Vasostriect® (Vasopressin Injection, USP) (NDA No. 204485) (Reviewer: Shari L. Targum, M.D.) (Reference ID: 3478975)	EAGLEVAS0034177	EAGLEVAS0034187	801, 802
DTX-254		Mark Cornell Manning et al., <i>Stability of Protein Pharmaceuticals: An Update</i> , 27(4) Pharm. Res. 544 (2010)	EAGLEVAS0038359	EAGLEVAS0038390	801, 802
DTX-255	9/2013	Vasopressin Injection, USP (Synthetic) Prescribing Information (revised: 09/2013) (Manufacturer: Fresenius Kabi USA, LLC)	EAGLEVAS0039503	EAGLEVAS0039508	801, 802
DTX-256	6/16/2014	The Joint Comm'n, <i>Preventing Infection from the Misuse of Vials</i> , 52 Sentinel Event Alert (June 16, 2014)	EAGLEVAS0055694	EAGLEVAS0055699	801, 802
DTX-257		<i>Compound Summary: Chlorobutanol</i> , PubChem (Nov. 9, 2019), https://pubchem.ncbi.nlm.nih.gov/compound/Chlorobutanol	EAGLEVAS0055824	EAGLEVAS0055872	801, 802
DTX-258	12/21/2018	FDA Response from Dr. J. Woodcock Granting Citizen Petition Submitted by K. Karst of Hyman, Phelps & McNamara P.C. Requesting That the FDA Determine Whether the Original Formulation of VASOSTRICT® (vasopressin injection), Approved under NDA No. 204485, Has Been Voluntarily Withdrawn for Reasons of Safety or Effectiveness and Confirm that the Agency Will Accept the Submission of ANDAs for Vasopressin Injection That References the Original Formulation of VASOSTRICT® as the Reference Listed Drug Basis of Submission (Docket No. FDA-2017-P-1096)	EAGLEVAS0055937	EAGLEVAS0055941	801, 802
DTX-259		Remington: Essentials of Pharmaceutics (Linda Felton ed., 2013)	EAGLEVAS0055942	EAGLEVAS0056724	801, 802
DTX-260		Shelley Chambers Fox, Remington Education: Pharmaceutics (2014)	EAGLEVAS0056725	EAGLEVAS0057285	801, 802
DTX-261		Pharmaceutical Preformulation and Formulation: A Practical Guide from Candidate Drug Selection to Commercial Dosage Form (Mark Gibson ed., 2004)	EAGLEVAS0057286	EAGLEVAS0057895	801, 802

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DTX-262		Sumie Yoshioka & Valentino J. Stella, Stability of Drugs and Dosage Forms (2002)	EAGLEVAS0058064	EAGLEVAS0058337	
DTX-263		Christina Avanti, Innovative Strategies for Stabilization of Therapeutic Peptides in Aqueous Formulations (2012)	EAGLEVAS0013669	EAGLEVAS0013825	801, 802
DTX-264	11/14/2018	Par Pharmaceutical, Inc. Stability Tables: SV 4200 Pitressin (Synthetic) USP, 20 Units/mL (Storage Conditions: 25C/60% RH, 30C/65% RH, 40C/75% RH) (Stock No. 2000179)	PAR-VASO_0052113	PAR-VASO_0052134	
DTX-265	11/21/2014	Par Pharmaceutical, Inc. Stability Tables: SV 4200 Pitressin (Synthetic) USP, 20 Units/mL (Storage Conditions: 25C/60% RH, 5C) (Stock Nos. 2000179, 2002132)	PAR-VASO_0053561	PAR-VASO_0053611	
DTX-266	1/8/2015	Par Pharmaceutical, Inc. Stability Tables: SV 4200 Pitressin (Synthetic) USP, 20 Units/mL (Storage Conditions: 25C/60% RH, 30C/65% RH, 40C/75% RH, 5C) (Stock No. 2002132)	PAR-VASO_0053873	PAR-VASO_0053898	
DTX-267	1/8/2015	Par Pharmaceutical, Inc. Stability Tables: SV 4200 Pitressin (Synthetic) USP, 20 Units/mL (Storage Conditions: 25C/60% RH, 30C/65% RH, 40C/75% RH, 5C) (Stock No. 2002132)	PAR-VASO_0057291	PAR-VASO_0057316	
DTX-268	9/25/2012	JHP Pharmaceuticals, LLC Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use (Form FDA 356h): Pitressin® (vasopressin injection, USP) (NDA No. 204485)	PAR-VASO_0072406	PAR-VASO_0072410	
DTX-269	4/16/2012	JHP Pharmaceuticals, LLC Product Development Technical Report (No. DEV-12-016): <i>Identification of Pitressin Impurities and Development of the AVP Impurity Marker Solution D009-19</i>	PAR-VASO_0073884	PAR-VASO_0073912	
DTX-270		JHP Pharmaceuticals NDA Module: 3.2.S.4.1 Specification - Drug Substance - Pitressin® (NDA No. 204485)	PAR-VASO_0073920	PAR-VASO_0073920	
DTX-271	3/26/1929	U.S. Trademark No. 254,507 to Parke, Davis & Co.	PAR-VASO_0076146	PAR-VASO_0076147	401, 402, 403, 801, 802
DTX-272	6/24/2013	Letter from G. Vasquez of JHP Pharmaceuticals, LLC to Dr. N. Stockbridge of the FDA re Request for Withdrawal of Proprietary Name: NDA 204485, SN 0014, VasoPrez® (Vasopressin Injection, USP), Synthetic	PAR-VASO_0077570	PAR-VASO_0077570	801, 802
DTX-273	6/3/2014	Letter from G. Vasquez of Par Sterile Products, LLC to Dr. N. Stockbridge of the FDA re Vasostrict® (vasopressin injection, USP) Synthetic NDA #204485, S/N 0031; Prior Approval Supplement: Refrigerated Storage Conditions and Shelf Life Extension	PAR-VASO_0079901	PAR-VASO_0079902	801, 802
DTX-274		Protein Formulation and Delivery (Eugene J. McNally & Jayne E. Hastedt eds., 2d ed. 2008)	PAR-VASO_0086302	PAR-VASO_0086673	801, 802
DTX-275	8/6/2008	JHP Pharmaceuticals, LLC Memorandum from D. Battisti to J. Gantenbein et al. re Vasopressin Information and Items for Discussion	PAR-VASO_0108603	PAR-VASO_0108616	801, 802
DTX-276	6/27/2019	Letter from Dr. M. Brivanlou of King & Spalding LLP to C. English of Par Sterile Products, LLC & the Legal Department of Par Pharmaceutical, Inc. re Notification of Paragraph IV Certification Regarding U.S. Patent Nos. 9,744, 239, 9,375,478, 9,687,526, 9,744,209, and 9,750,785 Pursuant to Section 505(b)(3) of the Federal Food, Drug, and Cosmetic Act	PAR-VASO_0248173	PAR-VASO_0248336	401, 402, 403, 801, 802, AA, Legal

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DTX-277	11/15/2019	Claims & Disclosures Table Prepared by Dr. Kinam Park, Ph.D. in Support of His Opening Report: <i>Appendix 1 - Pitressin® Public Use Bar & On-Sale Bar</i>			801, 802
DTX-278	11/15/2019	Claims & Disclosures Table Prepared by Dr. Kinam Park, Ph.D. in Support of His Opening Report: <i>Appendix 2 - American Regent Vasopressin Injection Public Use Bar & On-Sale Bar</i>			801, 802
DTX-279	11/15/2019	Claims & Disclosures Table Prepared by Dr. Kinam Park, Ph.D. in Support of His Opening Report: <i>Appendix 3 - Vasostrict® Public Use Bar & On-Sale Bar</i>			801, 802
DTX-280	11/15/2019	Claims & Disclosures Table Prepared by Dr. Kinam Park, Ph.D. in Support of His Opening Report: <i>Appendix 4 - Anticipation by Vasostrict® Labels</i>			801, 802
DTX-281	11/20/2019	Claims & Disclosures Table Prepared by Dr. Kinam Park, Ph.D. in Support of His Opening Report: <i>Appendix 5 - Publication Obviousness</i>			801, 802
DTX-282	10/2019	Curriculum Vitae of Kinam Park, Ph.D.			401, 402, 403, 801, 802
DTX-282A	12/2020	Updated Curriculum Vitae of Kinam Park, Ph.D.			
DTX-283	11/15/2019	List of Materials Considered for Opening Expert Report of Kinam Park, Ph.D.			801, 802
DTX-284	11/21/2019	Email from R. Rhoad of Dechert LLP to S. Kwon of Kirkland & Ellis LLP re Plaintiffs' Responses and Objections to Defendants' Interrogatories			401, 402, 403, 801, 802, AA, Legal
DTX-285	11/27/2019	Email from B. Lasky of Kirkland & Ellis LLP to M. Black of Dechert LLP re Plaintiffs' Response and Objections to Defendants' Interrogatories			401, 402, 403, 801, 802, AA, Legal
DTX-286	6/23/2017	OSO BioPharmaceuticals Manufacturing, LLC End-Product Data Collection Form: Vasopressin Injection, USP (Lot No. SVA003) (Customer: SAGENT Pharmaceuticals)	AMRIVAS0015410	AMRIVAS0015412	801, 802
DTX-287	6/2017	OSO BioPharmaceuticals Manufacturing, LLC End-Product Data Collection Form: Vasopressin Injection, USP (Lot No. SVA002) (Customer: SAGENT Pharmaceuticals)	AMRIVAS0015413	AMRIVAS0015415	801, 802
DTX-288	6/2017	OSO BioPharmaceuticals Manufacturing, LLC End-Product Data Collection Form: Vasopressin Injection, USP (Lot No. SVA001) (Customer: SAGENT Pharmaceuticals)	AMRIVAS0015416	AMRIVAS0015418	801, 802
DTX-289	4/4/2017	Albany Molecular Research Inc. Standard Operating Procedure Report (No. STA-EPX-0119): <i>Vasopressin Injection, USP, End Product Test Procedure</i> (Revision: 01)	AMRIVAS0035367	AMRIVAS0035389	801, 802
DTX-290	3/8/2019	OSO BioPharmaceuticals Manufacturing, LLC Master Batch Record (No. 10 869): Vasopressin Injection, USP, 0.0377 mg/mL (Lot No. SVA004) (Version: 4.0)	AMRIVAS0110443	AMRIVAS0110470	ID, 106, 801, 802, 1003

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EXHIBIT NO.	DATE	DESCRIPTION	BEG BATES NO.	END BATES NO.	OBJECTIONS
DTX-291		Compilation of Albany Molecular Research Inc. Laboratory Documents: Certificates of Analysis, End Product Data Collection Forms, and Other Miscellaneous Laboratory Documents for Vasopressin Injection, USP, 0.0377 mg/mL (Lot No. SVA004) (Customer: Eagle Pharmaceuticals)	AMRIVAS0110990	AMRIVAS0111046	401, 402, 403, 801, 802
DTX-292	3/7/2019	Albany Molecular Research Inc. Standard Operating Procedure Report (No. STA-IPX-0153): <i>Vasopressin Injection, USP, In-Process Test Procedure</i> (Revision: 01)	AMRIVAS0111171	AMRIVAS0111191	401, 402, 403, 801, 802
DTX-293	3/8/2019	Albany Molecular Research Inc. Standard Operating Procedure Report (No. STA-EPX-0119): <i>Vasopressin Injection, USP, End Product Test Procedure</i> (Revision: 04)	AMRIVAS0111192	AMRIVAS0111216	801, 802
DTX-294	3/8/2019	Albany Molecular Research Inc. End-Product Data Collection Form (No. STA-EPX-0119-F): Vasopressin Injection, USP (Lot No. Unspecified) (Customer: Eagle Pharmaceuticals) (Revision: 04)	AMRIVAS0111217	AMRIVAS0111222	801, 802
DTX-295	7/3/2019	Albany Molecular Research Inc. Standard Operating Procedure Report (No. STA-IPX-0153): <i>Vasopressin Injection, USP, In-Process Test Procedure</i> (Revision: 02)	AMRIVAS0111290	AMRIVAS0111312	401, 402, 403, 801, 802
DTX-296	7/3/2019	OSO BioPharmaceuticals Manufacturing, LLC Change Control Task Report (PR No. 674746): <i>Update SOPs STA-ATX-0126, STA-EPX-0119, and STA-IPX-0153</i> (with Updated SOP Report No. STA-EPX-0119 (Revision: 05) Enclosed Thereto)	AMRIVAS0111313	AMRIVAS0111347	801, 802
DTX-297	3/8/2019	OSO BioPharmaceuticals Manufacturing, LLC Master Batch Record (No. 10 869): Vasopressin Injection, USP, 0.0377 mg/mL (Lot No. SVA005) (Version: 4.0)	AMRIVAS0111402	AMRIVAS0111429	ID, 106, 801, 802, 1003
DTX-298	3/8/2019	OSO BioPharmaceuticals Manufacturing, LLC Master Batch Record (No. 10 869): Vasopressin Injection, USP, 0.0377 mg/mL (Lot No. SVA006) (Version: 4.0)	AMRIVAS0111430	AMRIVAS0111457	ID, 106, 801, 802, 1003
DTX-299		Compilation of Albany Molecular Research Inc. Laboratory Documents: Certificates of Analysis, End Product Data Collection Forms, and Other Miscellaneous Laboratory Documents for Vasopressin Injection, USP, 0.0377 mg/mL (Lot No. SVA005) (Customer: Eagle Pharmaceuticals)	AMRIVAS0111954	AMRIVAS0111973	401, 402, 403, 801, 802
DTX-300		Compilation of Albany Molecular Research Inc. Laboratory Documents: Certificates of Analysis, End Product Data Collection Forms, and Other Miscellaneous Laboratory Documents for Vasopressin Injection, USP, 0.0377 mg/mL (Lot No. SVA006) (Customer: Eagle Pharmaceuticals)	AMRIVAS0111974	AMRIVAS0112043	401, 402, 403, 801, 802
DTX-301	8/8/2019	OSO BioPharmaceuticals Manufacturing, LLC Master Batch Record (No. 10 869): Vasopressin Injection, USP, 0.0377 mg/mL (Lot No. Unspecified) (Version: 9.0)	AMRIVAS0114291	AMRIVAS0114391	801, 802
DTX-302	8/26/2019	OSO BioPharmaceuticals Manufacturing, LLC Out of Specification Report (PR No. 661354): <i>24 Month SVA001.5U Sample Failed pH Specification at 3.7</i>	AMRIVAS0114545	AMRIVAS0114548	106, 1003

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DTX-303		OSO BioPharmaceuticals Manufacturing, LLC Laboratory Notebook Excerpts Regarding Vasopressin Injection, USP Samples SVA001/002/003 (Document No. STA-PJN-0029) (Version: 3.0)	AMRIVAS0114554	AMRIVAS0114567	106, 1003
DTX-304	9/18/2019	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Conditions: 25C/60% RH Inverted, 25C/60% RH Upright) (Lot Nos. SVA007.25I, SVA007.25U)	AMRIVAS0117010	AMRIVAS0117013	401, 402, 403, 801, 802
DTX-305	10/9/2019	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Conditions: 25C/60% RH Inverted, 25C/60% RH Upright) (Lot Nos. SVA007.25I, SVA007.25U)	AMRIVAS0117014	AMRIVAS0117017	401, 402, 403, 801, 802
DTX-306	9/18/2019	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Conditions: 5C Inverted, 5C Upright) (Lot Nos. SVA007.5I, SVA007.5U)	AMRIVAS0117018	AMRIVAS0117021	401, 402, 403, 801, 802
DTX-307	9/18/2019	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Conditions: 25C/60% RH Inverted, 25C/60% RH Upright) (Lot Nos. SVA008.25I, SVA008.25U)	AMRIVAS0117022	AMRIVAS0117025	401, 402, 403, 801, 802
DTX-308	10/9/2019	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Conditions: 25C/60% RH Inverted, 25C/60% RH Upright) (Lot Nos. SVA008.25I, SVA008.25U)	AMRIVAS0117026	AMRIVAS0117029	401, 402, 403, 801, 802
DTX-309	9/18/2019	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Conditions: 5C Inverted, 5C Upright) (Lot Nos. SVA008.5I, SVA008.5U)	AMRIVAS0117030	AMRIVAS0117033	401, 402, 403, 801, 802
DTX-310	10/16/2019	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Conditions: 25C/60% RH Inverted, 25C/60% RH Upright) (Lot Nos. SVA009.25I, SVA009.25U)	AMRIVAS0117034	AMRIVAS0117037	401, 402, 403, 801, 802
DTX-311	10/16/2019	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Conditions: 5C Inverted, 5C Upright) (Lot Nos. SVA009.5I, SVA009.5U)	AMRIVAS0117038	AMRIVAS0117041	401, 402, 403, 801, 802
DTX-312		Eagle Pharmaceuticals ANDA Module: 3.2.P.1 Description and Composition of the Drug Product - Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0000458	EAGLEVAS0000463	801, 802
DTX-313		Eagle Pharmaceuticals ANDA Module: 3.2.P.2 Pharmaceutical Development - Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0000670	EAGLEVAS0000710	801, 802
DTX-314	9/18/2017	Albany Molecular Research Inc. Analytical Report (No. TM.04873): <i>Determination of Assay and Related Substances of Vasopressin Injection, USP by HPLC</i> (Revision: 01)	EAGLEVAS0000863	EAGLEVAS0000874	801, 802
DTX-315	9/18/2017	Albany Molecular Research Inc. Analytical Report (No. TM.04880): <i>Analysis of Chlorobutanol in Vasopressin Injection, USP by HPLC</i> (Revision: 01)	EAGLEVAS0000875	EAGLEVAS0000882	401, 402, 403, 801, 802
DTX-316		Eagle Pharmaceuticals ANDA Module: 3.2.P.3.3 Description of Manufacturing Process and Process Controls - Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS00001149	EAGLEVAS00001170	801, 802
DTX-317		Eagle Pharmaceuticals ANDA Module: 3.2.P.5.1 Specifications - Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS00001328	EAGLEVAS00001329	801, 802

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DTX-318	11/22/2016	Albany Molecular Research Inc. Analytical Report (No. ANC02239R): <i>Method Validation Report for Assay and Related Substances in Vasopressin Injection, USP by HPLC: Project 10972</i>	EAGLEVAS0001435	EAGLEVAS0001466	801, 802
DTX-319	3/30/2017	OSO BioPharmaceuticals Manufacturing, LLC Batch Release Documents: Vasopressin Injection, USP, 0.0377 mg/mL (Lot No. SVA001)	EAGLEVAS0001921	EAGLEVAS0002327	ID, 801, 802
DTX-320	3/30/2017	OSO BioPharmaceuticals Manufacturing, LLC Batch Release Documents: Vasopressin Injection, USP, 0.0377 mg/mL (Lot No. SVA002)	EAGLEVAS0002328	EAGLEVAS0002682	ID, 801, 802
DTX-321	3/30/2017	OSO BioPharmaceuticals Manufacturing, LLC Batch Release Documents: Vasopressin Injection, USP, 0.0377 mg/mL (Lot No. SVA003)	EAGLEVAS0002683	EAGLEVAS0003071	ID, 801, 802
DTX-322		Eagle Pharmaceuticals ANDA Module: 3.2.P.3.4 Controls of Critical Steps and Intermediates - Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0045429	EAGLEVAS0045443	801, 802
DTX-323		Eagle Pharmaceuticals ANDA Module: 3.2.P.3.3 Description of Manufacturing Process and Process Controls - Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0045476	EAGLEVAS0045508	801, 802
DTX-324	8/29/2019	OSO BioPharmaceuticals Manufacturing, LLC Master Batch Record (No. 10 869): Vasopressin Injection, USP, 0.0377 mg/mL (Lot No. Unspecified) (Version: Proposed Commercial)	EAGLEVAS0045509	EAGLEVAS0045605	401, 402, 403, 801, 802
DTX-325	8/9/2019	Albany Molecular Research Inc. Standard Operating Procedure Report (No. STA-IPX-0153): <i>Vasopressin Injection, USP, In-Process Test Procedure</i> (Revision: 04)	EAGLEVAS0045607	EAGLEVAS0045632	401, 402, 403, 801, 802
DTX-326	7/24/2019	Albany Molecular Research Inc. Summary Report: <i>Eagle Pharmaceutical's Vasopressin (SVA) Engineering Run (V1926) Summary Report</i>	EAGLEVAS0045725	EAGLEVAS0045847	401, 402, 403, 801, 802
DTX-327		Eagle Pharmaceuticals ANDA Module: 3.2.P.5.1 Specifications - Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0046173	EAGLEVAS0046175	801, 802
DTX-328		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2019 Optimization Batch, Batch SV004 Inverted Position, DOM: 15Mar2019: Long Term (2° to 8°C) Stability Data, Stability Protocol PD SVA-04 Rev01, Stability Start 02Apr2019</i>	EAGLEVAS0047304	EAGLEVAS0047310	801, 802
DTX-329		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2019 Optimization Batch, Batch SV005 Inverted Position, DOM: 03Apr2019: Long Term (2° to 8°C) Stability Data, Stability Protocol PD SVA-04 Rev01, Stability Start 17Apr2019</i>	EAGLEVAS0047311	EAGLEVAS0047317	801, 802
DTX-330		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2019 Optimization Batch, Batch SV006 Inverted Position, DOM: 08Apr2019: Long Term (2° to 8°C) Stability Data, Stability Protocol PD SVA-04 Rev01, Stability Start 17Apr2019</i>	EAGLEVAS0047318	EAGLEVAS0047324	801, 802
DTX-331		Eagle Pharmaceuticals ANDA Module: 3.2.P.8.1 Stability Summary and Conclusion - Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0047328	EAGLEVAS0047355	801, 802

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DTX-332	8/22/2019	OSO BioPharmaceuticals Manufacturing, LLC Batch Release Documents: Vasopressin Injection, USP, 0.0377 mg/mL (Lot No. SVA007)	EAGLEVAS0047362	EAGLEVAS0048071	ID, 801, 802
DTX-333	8/22/2019	OSO BioPharmaceuticals Manufacturing, LLC Batch Release Documents: Vasopressin Injection, USP, 0.0377 mg/mL (Lot No. SVA008)	EAGLEVAS0048072	EAGLEVAS0048666	ID, 801, 802
DTX-334	9/3/2019	OSO BioPharmaceuticals Manufacturing, LLC Batch Release Documents: Vasopressin Injection, USP, 0.0377 mg/mL (Lot No. SVA009)	EAGLEVAS0048667	EAGLEVAS0049378	ID, 801, 802
DTX-335		JHP Pharmaceuticals, LLC Complete Response to Information Request Received March 7, 2013 from the FDA re NDA No. 204485	PAR-VASO_0077758	PAR-VASO_0077767	
DTX-336	12/23/2019	List of Materials Considered for Rebuttal Expert Report of Kinam Park, Ph.D.			801, 802
DTX-337		<i>Amino Acid Explorer: Substitutions in BLOSUM62 for Asparagine</i> , NCBI Structures, https://www.ncbi.nlm.nih.gov/Class/Structure/aa/aa_explorer.cgi	EAGLEVAS0058375	EAGLEVAS0058375	801, 802
DTX-338		G. P. S. Raghava & Geoffrey J. Barton, <i>Quantification of the Variation in Percentage Identity for Protein Sequence Alignments</i> , 7(415) BMC Bioinformatics (2006)	EAGLEVAS0058376	EAGLEVAS0058379	401, 402, 403, 801, 802
DTX-339		AppliChem, <i>Biological Buffers</i> (2008)	EAGLEVAS0058380	EAGLEVAS0058399	801, 802
DTX-340		Eagle Pharmaceuticals ANDA Module: 3.2.P.5.5 Characterization of Impurities - Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0001749	EAGLEVAS0001754	801, 802
DTX-341		Chandra Mohan, <i>Buffers: A Guide for the Preparation and Use of Buffers in Biological Systems</i> , Calbiochem® Biochems. (2006)	EAGLEVAS0014396	EAGLEVAS0014433	801, 802
DTX-342	4/5/2019	Declaration of Mansoor M. Amiji, Ph.D., R.Ph. Regarding Claim Construction, Submitted as Exhibit 25 to the Parties' Joint Claim Construction Appendix (D.I. 62)			801, 802
DTX-343		Excerpts of FDA Approval Package for VASOSTRICT® (vasopressin injection) (NDA No. 204485), Submitted as Exhibit 30 to the Parties' Joint Claim Construction Appendix (D.I. 62)			
DTX-344	4/29/2019	Supplemental Declaration of Mansoor M. Amiji, Ph.D., R.Ph. Regarding Claim Construction, Submitted as Exhibit 44 to the Parties' Joint Claim Construction Appendix (D.I. 62)			801, 802
DTX-345		Alex C. W. May, <i>Percent Sequence Identity: The Need to Be Explicit</i> , 12 Structure 737 (2004)	EAGLEVAS0058402	EAGLEVAS0058403	401, 402, 403, 801, 802
DTX-346		IUPAC-IUB Comm'n on Biochem. Nomenclature, <i>Rules for Naming Synthetic Modifications of Natural Peptides: Tentative Rules</i> , 1 Eur. J. Biochem. 379 (1967)	EAGLEVAS0058404	EAGLEVAS0058406	401, 402, 403, 801, 802
DTX-347	1/20/2020	List of Materials Considered for Reply Expert Report of Dr. Mansoor M. Amiji, Ph.D., R.Ph. Concerning Invalidity of U.S. Patent Nos. 9,687,526; 9,744,209; and 9,750,785			801, 802
DTX-348		Henry L. Alder & Edward B. Roessler, <i>Student's t-Distribution. Small Sample Methods</i> , in <i>Introduction to Probability and Statistics</i> 171 (6th ed. 1977)	EAGLEVAS0058352	EAGLEVAS0058374	801, 802

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EXHIBIT NO.	DATE	DESCRIPTION	BEG BATES NO.	END BATES NO.	OBJECTIONS
DTX-349	1/10/2020	Plaintiffs' Answer to Defendant's Amended Counterclaims (D.I. 167)			401, 402, 403, 801, 802, AA, Legal
DTX-350		Par Pharmaceutical, Inc. Product Development Stability Summary: <i>Room Temperature Evaluation of Stability Studies for Vasostriect® (vasopressin injection, USP) pH 3.8 Acetate Buffer, Single Dose (Perservative Free) (Stock # 2002501)</i>	PAR-VASO_0030563	PAR-VASO_0030582	
DTX-351	1/20/2020	List of Materials Considered for Reply Expert Report of Leonard J. Chyall, Ph.D.			801, 802
DTX-352	10/9/2019	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Conditions: 25C/60% RH Inverted, 25C/60% RH Upright) (Lot Nos. SVA004.25I, SVA004.25U)	AMRIVAS0117066	AMRIVAS0117069	401, 402, 403, 801, 802
DTX-353	10/9/2019	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Conditions: 5C Inverted, 5C Upright) (Lot Nos. SVA004.5I, SVA004.5U)	AMRIVAS0117072	AMRIVAS0117075	401, 402, 403, 801, 802
DTX-354	10/23/2019	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Conditions: 25C/60% RH Inverted, 25C/60% RH Upright) (Lot Nos. SVA005.25I, SVA005.25U)	AMRIVAS0117076	AMRIVAS0117079	401, 402, 403, 801, 802
DTX-355	10/23/2019	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Conditions: 5C Inverted, 5C Upright) (Lot Nos. SVA005.5I, SVA005.5U)	AMRIVAS0117084	AMRIVAS0117087	401, 402, 403, 801, 802
DTX-356	10/23/2019	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Conditions: 25C/60% RH Inverted, 25C/60% RH Upright) (Lot Nos. SVA006.25I, SVA006.25U)	AMRIVAS0117088	AMRIVAS0117091	401, 402, 403, 801, 802
DTX-357	10/23/2019	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Conditions: 5C Inverted, 5C Upright) (Lot Nos. SVA006.5I, SVA006.5U)	AMRIVAS0117096	AMRIVAS0117099	401, 402, 403, 801, 802
DTX-358	10/28/2019	Eagle Pharmaceuticals Inc.'s First Amended Answer to Complaint and Counterclaims (D.I. 136)			401, 402, 403, 801, 802, AA, Legal
DTX-359	6/7/2017	Par Sterile Products, LLC Stability Tables: <i>Tabulated Stability Data through 23-Month Interval: Vasostriect (Vasopressin Injection, USP), 20 Units per mL, 1mL (New Formulation): Stock No. 2002501</i>	PAR-VASO_0024408	PAR-VASO_0024421	
DTX-360	5/4/2017	Par Pharmaceutical, Inc. Memorandum from S. Mikolajczak to A. Velez re Vasostriect - Stability Data for Annual Report	PAR-VASO_0050216	PAR-VASO_0050319	
DTX-361		Karlis Adamsons, Jr. et al., <i>The Stability of Natural and Synthetic Neurohypophyseal Hormones</i> in Vitro, 63(5) Endocrinology 679 (1958)	EAGLEVAS0038897	EAGLEVAS0038905	
DTX-362		Lewis P. Stratton et al., <i>Controlling Deamidation Rates in a Model Peptide: Effects of Temperature, Peptide Concentration, and Additives</i> , 90(12) J. Pharm. Scis. 2141 (2001)	PAR-VASO_0291795	PAR-VASO_0291802	
DTX-363		Wei Wang, <i>Instability, Stabilization, and Formulation of Liquid Protein Pharmaceuticals</i> , 185 Int'l J. Pharm. 129 (1999)	PAR-VASO_0291664	PAR-VASO_0291723	
DTX-364		List of Materials Considered for Reply Expert Report of Kinam Park, Ph.D.			801, 802

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EXHIBIT NO.	DATE	DESCRIPTION	BEG BATES NO.	END BATES NO.	OBJECTIONS
DTX-365	8/26/2019	Plaintiffs' Second Supplemental Objections and Responses to Eagle Pharmaceuticals Inc.'s First Set of Interrogatories (Nos. 4-10, 12-13)			401, 402, 403, 801, 802, AA, Legal
DTX-366	10/2/2019	Email from R. Rhoad of Dechert LLP to A. Cade of Kirkland & Ellis LLP re Plaintiffs' Responses and Objections to Defendants' Interrogatories			401, 402, 403, 801, 802, AA, Legal
DTX-367		Sharmistha Bhadra et al., <i>A Wireless Passive Sensor for Temperature Compensated Remote pH Monitoring</i> , 13(6) IEEE Sensors J. 2428 (2013)	EAGLEVAS0033135	EAGLEVAS0033143	801, 802
DTX-368	10/2013	NOVAPLUS® (vasopressin injection, USP) Synthetic Prescribing Information (revised: 10/2013) (Manufacturer: Fresenius Kabi USA, LLC)	EAGLEVAS0013874	EAGLEVAS0013879	801, 802
DTX-369		Z. Grzonka et al., <i>In Vitro Degradation of Some Arginine-Vasopressin Analogs by Homogenates of Rat Kidney, Liver and Serum</i> , 4(5) Peptide Res. 270 (1991)	EAGLEVAS0013880	EAGLEVAS0013884	801, 802
DTX-370		Philip E. Aylward et al., <i>Effects of Vasopressin on the Circulation and Its Baroreflex Control in Healthy Men</i> , 73(6) Circulation 1145 (1986)	EAGLEVAS0013826	EAGLEVAS0013836	801, 802
DTX-371		Antonio Rodriguez-Nunez et al., <i>Terlipressin Continuous Infusion: Please Mind the Solvent!</i> , 10(6) Current Drug Targets 577 (2009)	EAGLEVAS0013986	EAGLEVAS0013986	801, 802
DTX-372	10/2015	U.S. Food Drug & Admin., <i>Selection of the Appropriate Package Type Terms and Recommendations for Labeling Injectable Medical Products Packaged in Multiple-Dose, Single-Dose, and Single-Patient-Use Containers for Human Use: Guidance for Industry: Draft Guidance</i> (Oct. 2015)	EAGLEVAS0013863	EAGLEVAS0013873	801, 802
DTX-373	5/24/2013	FDA Clinical Pharmacology Review of Proposed Drug Product, Pitressin® (Vasopressin Injection, USP) (NDA No. 204485) (Reviewer: Peter Hinderling, M.D.) (Reference ID: 3313873)	EAGLEVAS0013938	EAGLEVAS0013985	801, 802
DTX-374	11/2015	VASOSTRICT® (vasopressin injection) Prescribing Information (revised: 11/2015)	PAR-VASO_0014523	PAR-VASO_0014524	
DTX-375	12/2016	VASOSTRICT® (vasopressin injection) Prescribing Information (revised: 12/2016)	PAR-VASO_0067973	PAR-VASO_0067979	
DTX-376		R. Phillip Dellinger et al., <i>Surviving Sepsis Campaign: International Guidelines for Management of Severe Sepsis and Septic Shock: 2012</i> , 41(2) Critical Care Med. 580 (2013)	EAGLEVAS0038444	EAGLEVAS0038501	801, 802
DTX-377	4/17/2014	Approval Package for: APPLICATION NUMBER: 204485Orig1s000, U.S. Food & Drug Admin. (Apr. 17, 2014), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/204485Orig1s000Appov.pdf	AMRIVAS0070476	AMRIVAS0070482	106, 801, 802, 1003
DTX-378		Kids Intensive Care & Decision Support, http://web.archive.org/web/20130409160131/http://kids.bch.nhs.uk/			801, 802, 901, 902

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EXHIBIT NO.	DATE	DESCRIPTION	BEG BATES NO.	END BATES NO.	OBJECTIONS
DTX-379		<i>KIDS Clinical Guidelines</i> , Kids Intensive Care & Decision Support, http://web.archive.org/web/20150828035138/http://kids.bch.nhs.uk/healhtcare-professionals-2/clinical-guidelines			801, 802, 901, 902
DTX-380		Full Abbreviated New Drug Application No. 211538	EAGLEVAS0000001	EAGLEVAS0013662	
DTX-381		Amended Abbreviated New Drug Application No. 211538: Complete Response Submission	EAGLEVAS0043551	EAGLEVAS0051562	
DTX-382	5/2/2017	Applicants' Response to Non-Final Office Action, in re Application of: Matthew Kenney (U.S. Patent Appl. No. 15/289,640)	PAR-VASO-0004862	PAR-VASO-0004875	
DTX-383	8/28/2018	Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC's First Set of Interrogatories to Eagle Pharmaceuticals (Nos. 1-10)			401, 402, 403, 801, 802, AA, Legal
DTX-384	8/29/2019	Plaintiffs' Opening Claim Construction Brief, <i>Par Pharm., Inc. v. Sandoz Inc.</i> , No. 3:18-cv-14895-BRM-DEA (D.N.J. Aug. 29, 2019), ECF No. 52			401, 402, 403, 801, 802, AA, Legal
DTX-385	10/28/2019	Plaintiffs' Claim Construction Response Brief, <i>Par Pharm., Inc. v. Sandoz Inc.</i> , No. 3:18-cv-14895-BRM-DEA (D.N.J. Oct. 28, 2019), ECF No. 63			401, 402, 403, 801, 802, AA, Legal
DTX-386	11/6/2018	Plaintiffs' Initial Disclosures Pursuant to Fed. R. Civ. P. 26(a)(1)(A)			401, 402, 403, 801, 802, AA, Legal
DTX-387	12/19/2018	Plaintiffs' Initial Infringement Contentions, and Exhibits Thereto			401, 402, 403, 801, 802, AA, Legal
DTX-388	12/19/2017	Services and Commercial Supply Term Sheet by and among Albany Molecular Research Inc. and Eagle Pharmaceuticals Inc., dated as of December 19, 2017	EAGLEVAS0027754	EAGLEVAS0027758	801, 802
DTX-389	8/15/2007	King Pharmaceuticals, Inc. Research Report (No. 703-00133): <i>Interim Report for the Assessment of Potential Stoppers for Pitressin</i>	PAR-VASO_0104860	PAR-VASO_0104894	401, 402, 403, 801, 802
DTX-390		Parkedale Pharmaceuticals Product Validation Addendum: Pitressin (Synthetic) USP Bulk Solution, 20 Units per 1 mL (Stock No. AMP 4200: 4200X912)	PAR-VASO_0116219	PAR-VASO_0116254	401, 402, 403, 801, 802
DTX-391		Parkedale Pharmaceuticals Product Validation Addendum: SV 4200 Pitressin (Synthetic) USP, 20 Units per 1 mL and AMP 4200 Pitressin (Synthetic) USP, 20 Units per 1 mL (Stock Nos. 4200X955, 4200X912)	PAR-VASO_0116255	PAR-VASO_0116265	401, 402, 403, 801, 802
DTX-392		Eagle Pharmaceuticals ANDA Module: 3.2.S.4.3 Validation of Analytical Procedures - Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0051026	EAGLEVAS0051027	801, 802
DTX-393		Vasopressin Injection, USP Proposed Package Labeling (Previously Submitted Version)	EAGLEVAS0043562	EAGLEVAS0043564	801, 802
DTX-394		Vasopressin Injection, USP Proposed Package Labeling (Amended Version)	EAGLEVAS0043565	EAGLEVAS0043565	801, 802
DTX-395	9/2019	VASOPRESSIN Injection Prescribing Information (revised: 09/2019)	EAGLEVAS0043569	EAGLEVAS0043571	801, 802
DTX-396	5/2018	VASOPRESSIN Injection Prescribing Information (revised: 05/2018)	EAGLEVAS0043572	EAGLEVAS0043594	106, 401, 402, 403, 801, 802, 1003
DTX-397		Chemical Compound Formula: 8-arginine-vasopressin's Peptide Sequence	EAGLEVAS0043595	EAGLEVAS0043595	801, 802, 901, 902

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DTX-398		Vasopressin Injection, USP Proposed Package Labeling (Color Version)	EAGLEVAS0043596	EAGLEVAS0043596	801, 802
DTX-399		Vasopressin Injection, USP Proposed Package Labeling (Color Version)	EAGLEVAS0043597	EAGLEVAS0043597	801, 802
DTX-400		Eagle Pharmaceuticals ANDA Submission: Side by Side Comparison - Proposed Labeling vs. Last Submitted - Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0043598	EAGLEVAS0043605	801, 802
DTX-401	9/11/2019	Eagle Pharmaceuticals, Inc. Application to Market a New or Abbreviated New Drug or Biologic for Human Use (Form FDA 356h): Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0043606	EAGLEVAS0043613	801, 802
DTX-402		Eagle Pharmaceuticals ANDA Module: 1.3.1.2 Change in Contact/Agent - Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0043664	EAGLEVAS0043664	801, 802
DTX-403		Eagle Pharmaceuticals ANDA Module: 1.3.2 Field Copy Certification - Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0043665	EAGLEVAS0043665	801, 802
DTX-404		Eagle Pharmaceuticals ANDA Resubmission: Major Complete Response Amendment - Response to CRL dated 18 Jan 2019 - Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0043666	EAGLEVAS0043669	106, 401, 402, 403, 801, 802, 1003
DTX-405		Eagle Pharmaceuticals ANDA Module: 2.3.S Drug Substance - Quality Overall Summary - Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0043791	EAGLEVAS0043830	801, 802
DTX-406		Eagle Pharmaceuticals ANDA Module: 3.2.P.2 Pharmaceutical Development - Vasopressin Injection, USP (ANDA No.211538)	EAGLEVAS0045321	EAGLEVAS0045321	801, 802
DTX-407		Eagle Pharmaceuticals ANDA Module: 3.2.P.3.2 Batch Formula - Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0045423	EAGLEVAS0045423	801, 802
DTX-408		Eagle Pharmaceuticals ANDA Module: 3.2.P.3.1 Manufacturers - Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0045474	EAGLEVAS0045475	801, 802
DTX-409		Eagle Pharmaceuticals ANDA Module: 3.2.P.3.5.3 Thermal Qualification of the Cycle - Steriline Depyrogenation Tunnel - Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0045633	EAGLEVAS0045697	401, 402, 801, 802
DTX-410	7/24/2019	Albany Molecular Research Inc. Summary Report: <i>Eagle Pharmaceutical's Vasopressin (SVA) Adsorption (V1920) Summary Report</i>	EAGLEVAS0045699	EAGLEVAS0045724	401, 402, 801, 802
DTX-411		Eagle Pharmaceuticals ANDA Module: 3.2.P.3.5.1 Thermal Qualification of the Cycle - AMSCO 2.1 Autoclave - Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0045848	EAGLEVAS0045938	401, 402, 801, 802
DTX-412		Eagle Pharmaceuticals ANDA Module: 3.2.P.4.2 Analytical Procedures - Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0045939	EAGLEVAS0045939	401, 402, 801, 802
DTX-413	7/2019	Albany Molecular Research Inc. Certificate of Analysis: Glacial Acetic Acid (Lot No. A049052)	EAGLEVAS0045958	EAGLEVAS0045964	401, 402, 801, 802
DTX-414		Eagle Pharmaceuticals ANDA Module: 3.2.P.4.4 Justification of Specifications - Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0045975	EAGLEVAS0045976	401, 402, 801, 802
DTX-415		Eagle Pharmaceuticals ANDA Module: 3.2.P.4.1 Specifications - Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0045978	EAGLEVAS0045981	401, 402, 801, 802

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DTX-416	6/27/2019	OSO Biopharmaceuticals Manufacturing, LLC Material Specification Form (No. SR9-CH0002.1): Chlorobutanol, Hydrous, NF (Manufacturer: Athenstaedt)	EAGLEVAS0045982	EAGLEVAS0045986	401, 402, 801, 802
DTX-417	6/27/2019	OSO Biopharmaceuticals Manufacturing, LLC Material Specification Form (No. SR9-GL00004.1): Glacial Acetic Acid, USP, EP (Manufacturer: Celanese Limited)	EAGLEVAS0045987	EAGLEVAS0045989	401, 402, 801, 802
DTX-418		Eagle Pharmaceuticals ANDA Module: 3.2.P.4.3 Validation of Analytical Procedures - Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0046172	EAGLEVAS0046172	401, 402, 801, 802
DTX-419		Eagle Pharmaceuticals ANDA Module: 3.2.P.5.2 Analytical Procedures - Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0046176	EAGLEVAS0046177	801, 802
DTX-420	1/15/2019	Albany Molecular Research Inc. Analytical Report (No. ALB-MVR-0018): <i>Method Validation Report for Determination of Assay and Related Substances of Vasopressin Injection, USP by HPLC (Part-1): Project 12226</i>	EAGLEVAS0046225	EAGLEVAS0046289	801, 802
DTX-421	12/14/2018	Albany Molecular Research Inc. Analytical Report (No. ALB-MVR-0018): <i>Method Validation Report for Determination of Assay and Related Substances of Vasopressin Injection, USP by HPLC (Part-2): Project 12226</i>	EAGLEVAS0046290	EAGLEVAS0046307	801, 802
DTX-422	1/16/2019	Albany Molecular Research Inc. Method Transfer Protocol Report (Protocol No. MT18-042): <i>Assay and Related Substances by HPLC for Vasopressin Injection, USP, Drug Product (Revision: 2.0)</i>	EAGLEVAS0046308	EAGLEVAS0046405	801, 802
DTX-423	8/7/2019	Albany Molecular Research Inc. Sample Information Report: <i>Sample and Standard Spectra and Chromatograms</i> (Samples: Vasopressin Injection, USP Reference Standard (Lot No. R09120) and Vasopressin Injection, USP End Product (Lot No. SVA007))	EAGLEVAS0046406	EAGLEVAS0046415	401, 402, 801, 802
DTX-424		Eagle Pharmaceuticals ANDA Module: 3.2.P.5.3 Validation of Analytical Procedures - Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0046416	EAGLEVAS0046418	801, 802
DTX-425		Eagle Pharmaceuticals ANDA Module: 3.2.P.5.4 Batch Analyses - Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0046427	EAGLEVAS0046427	801, 802
DTX-426	4/23/2019	OSO BioPharmaceuticals Manufacturing, LLC Certificate of Analysis: Vasopressin Injection, USP, 0.0377 mg/mL (Lot No. SVA004)	EAGLEVAS0046428	EAGLEVAS0046430	401, 402, 403, 801, 802
DTX-427	5/8/2019	OSO BioPharmaceuticals Manufacturing, LLC Certificate of Analysis: Vasopressin Injection, USP, 0.0377 mg/mL (Lot No. SVA005)	EAGLEVAS0046431	EAGLEVAS0046433	401, 402, 403, 801, 802
DTX-428	5/6/2019	OSO BioPharmaceuticals Manufacturing, LLC Certificate of Analysis: Vasopressin Injection, USP, 0.0377 mg/mL (Lot No. SVA006)	EAGLEVAS0046434	EAGLEVAS0046436	401, 402, 403, 801, 802
DTX-429	8/16/2019	OSO BioPharmaceuticals Manufacturing, LLC Certificate of Analysis: Vasopressin Injection, USP, 0.0377 mg/mL (Lot No. SVA007)	EAGLEVAS0046437	EAGLEVAS0046440	401, 402, 403, 801, 802

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DTX-430	8/16/2019	OSO BioPharmaceuticals Manufacturing, LLC Certificate of Analysis: Vasopressin Injection, USP, 0.0377 mg/mL (Lot No. SVA008)	EAGLEVAS0046441	EAGLEVAS0046444	401, 402, 403, 801, 802
DTX-431	8/28/2019	OSO BioPharmaceuticals Manufacturing, LLC Certificate of Analysis: Vasopressin Injection, USP, 0.0377 mg/mL (Lot No. SVA009)	EAGLEVAS0046445	EAGLEVAS0046448	401, 402, 403, 801, 802
DTX-432		Eagle Pharmaceuticals ANDA Module: 3.2.P.5.5 Characterizations of Impurities - Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0046449	EAGLEVAS0046457	801, 802
DTX-433	9/9/2019	Eagle Pharmaceuticals, Inc. Technical Report (No. ETR134): <i>Comparative Impurity Profile Characterization of Eagle Vasopressin Injection, USP Drug Product and Vasotriect® Samples by HPLC-MS and HPLC-UV</i> (Version: 1.0)	EAGLEVAS0046458	EAGLEVAS0046602	801, 802
DTX-434	6/5/2019	Novatia Analytical Report Prepared for Eagle Pharmaceuticals, Inc.: <i>Identification of 1.16 RRT Impurity in Vasopressin Drug Product</i>	EAGLEVAS0046603	EAGLEVAS0046632	801, 802
DTX-435	8/20/2019	Eagle Pharmaceuticals, Inc. Technical Report (No. ETR132): <i>Assessment of the Trisulfide Vasopressin Impurity in Vasopressin Injection, USP: Identification, Statistical Evaluation and Specification Recommendation</i> (Version: 1.0)	EAGLEVAS0046633	EAGLEVAS0046742	801, 802
DTX-436		Eagle Pharmaceuticals ANDA Module: 3.2.P.5.6 Justification of Specifications - Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0046743	EAGLEVAS0046751	801, 802
DTX-437	8/21/2019	Alcami Analytical Test Report (No. RPT88445.01): Vasopressin Injection, USP, 0.0377 mg/mL (Lot No. L-100 NB-19-057/059) (Customer: Eagle Pharmaceuticals, Inc.)	EAGLEVAS0046752	EAGLEVAS0046760	401, 402, 801, 802
DTX-438	8/27/2019	Eagle Pharmaceuticals Inc. Statistical Analysis Report: <i>Vasopressin Injection, USP Stability Analysis: - A Statistical Evaluation of Assay and Total Impurities</i> (Version: 2.0)	EAGLEVAS0047230	EAGLEVAS0047241	801, 802
DTX-439	8/27/2019	Eagle Pharmaceuticals Inc. Statistical Analysis Report: <i>Vasopressin Injection, USP Stability Analysis: - A Statistical Evaluation of pH</i> (Version: 2.0)	EAGLEVAS0047242	EAGLEVAS0047248	801, 802
DTX-440		Eagle Pharmaceuticals ANDA Module: 3.2.P.8.2 Post-Approval Stability Protocol and Stability Commitment - Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0047249	EAGLEVAS0047252	801, 802
DTX-441		Eagle Pharmaceuticals ANDA Module: 3.2.P.8.3 Stability Data - Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0047270	EAGLEVAS0047273	801, 802
DTX-442		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasotriect® Injection, RLD, USP 0.0377 mg/mL, Batch 307503*, 10mL Fill Vials, Inverted Position, DOM: Mar2018: 25°C/60% RH Stability Data, Stability Protocol PD SVA-03 Rev01, Stability Start 27Mar2019</i>	EAGLEVAS0047325	EAGLEVAS0047327	401, 402, 403, 801, 802
DTX-443		Eagle Pharmaceuticals ANDA Module: 3.2.R.1.P.1 Executed Batch Records for Drug Product - Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0047356	EAGLEVAS0047361	801, 802
DTX-444		Eagle Pharmaceuticals ANDA Module: 3.2.S.1.3 General Properties - Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0049433	EAGLEVAS0049436	801, 802

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DTX-445		Eagle Pharmaceuticals ANDA Module: 3.2.S.1.1 Nomenclature - Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0049437	EAGLEVAS0049437	801, 802
DTX-446	10/25/2017	Letter from Dr. S. Kotwal of Hemmo Pharmaceuticals Private Limited to DMF Staff re Vasopressin USP with DMF Number 032146	EAGLEVAS0049441	EAGLEVAS0049441	801, 802
DTX-447		Eagle Pharmaceuticals ANDA Module: 3.2.S.2.1 Manufacturer(s) - Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0049442	EAGLEVAS0049443	401, 402, 801, 802
DTX-448		Hemmo Pharmaceuticals DMF Submission: Impurity Reference Standards Vasopressin Injection, USP (DMF No. 032146)	EAGLEVAS0049444	EAGLEVAS0049752	401, 402, 801, 802
DTX-449		Eagle Pharmaceuticals ANDA Module: 3.2.S.3.1 Elucidation of Structure and Other Characteristics (Vasopressin, 8-L-Arginine, USP) - Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0049753	EAGLEVAS0049758	401, 402, 801, 802
DTX-450	4/29/2019	Eagle Pharmaceuticals, Inc. Technical Report (No. ETR129): <i>Characterization of Hemmo Vasopressin, 8-L-Arginine Drug Substance</i> (Version: 1.0)	EAGLEVAS0049759	EAGLEVAS0050150	401, 402, 801, 802
DTX-451		Eagle Pharmaceuticals ANDA Module: 3.2.S.3.2 Impurities (Vasopressin, USP) - Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0050151	EAGLEVAS0050166	801, 802
DTX-452		OSO BioPharmaceuticals Manufacturing, LLC Certificate of Analysis: Vasopressin Injection, USP (Lot No. Unspecified) (Manufacturer: Hemmo Pharmaceuticals Private Limited)	EAGLEVAS0050167	EAGLEVAS0050169	401, 402, 801, 802, 1003
DTX-453		Eagle Pharmaceuticals ANDA Module: 3.2.S.4.1 Specification - Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0050170	EAGLEVAS0050172	801, 802
DTX-454		Eagle Pharmaceuticals ANDA Module: 3.2.S.4.2 Analytical Procedures - Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0050173	EAGLEVAS0050174	801, 802
DTX-455	8/2/2019	Albany Molecular Research Inc. Standard Operating Procedure Report (No. STA-ATX-0126): <i>Acceptance Criteria for Vasopressin API, USP</i> (Revision: 04)	EAGLEVAS0050175	EAGLEVAS0050203	801, 802
DTX-456	6/29/2019	Hemmo Pharmaceuticals Private Limited Analytical Report (Protocol No. QA/VAL/MV/19-020): <i>Protocol for Method Validation of Related Substances of Vasopressin USP by HPLC (TM-VP-RS-04) Method</i> (Revision: 00)	EAGLEVAS0050392	EAGLEVAS0050460	801, 802
DTX-457	7/17/2019	Hemmo Pharmaceuticals Private Limited Analytical Report (Protocol No. QA/VAL/MV/19-023): <i>Protocol for Method Validation of Related Substances of Vasopressin USP by HPLC (TM-VP-RS-05) Method</i> (Revision: 01)	EAGLEVAS0050461	EAGLEVAS0050827	801, 802
DTX-458	12/4/2018	Alcami Method Validation Report (No. RPT78661.01): <i>Method Validation for the Amino Acid Composition of Vasopressin in Vasopressin API</i>	EAGLEVAS0050828	EAGLEVAS0050855	401, 402, 801, 802
DTX-459		Eagle Pharmaceuticals ANDA Module: 3.2.S.4.4 Batch Analyses - Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0051028	EAGLEVAS0051028	801, 802
DTX-460	7/26/2019	Albany Molecular Research Inc. Certificate of Analysis: Vasopressin, USP (Lot No. A043172) (Manufacturer: Hemmo Pharmaceuticals Private Limited)	EAGLEVAS0051029	EAGLEVAS0051035	801, 802

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DTX-461	8/23/2019	Albany Molecular Research Inc. Certificate of Analysis: Vasopressin, USP (Lot No. A049473) (Manufacturer: Hemmo Pharmaceuticals Private Limited)	EAGLEVAS0051036	EAGLEVAS0051038	801, 802
DTX-462	8/20/2019	Hemmo Pharmaceuticals Private Limited Certificate of Analysis: Vasopressin USP Powder (Synthetic) (Batch No. VP-010619)	EAGLEVAS0051039	EAGLEVAS0051042	801, 802
DTX-463	5/2/2019	Hemmo Pharmaceuticals Private Limited Certificate of Analysis: Vasopressin USP Powder (Synthetic) (Batch No. VP-041217)	EAGLEVAS0051043	EAGLEVAS0051045	801, 802
DTX-464		Eagle Pharmaceuticals ANDA Module: 3.2.S.4.5 Justification of Specification - Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0051046	EAGLEVAS0051053	801, 802
DTX-465	5/24/2019	Hemmo Pharmaceuticals Private Limited Certificate of Analysis: Vasopressin Bis-SH (Powder Synthetic) (Batch No. VA-020616)	EAGLEVAS0051068	EAGLEVAS0051076	801, 802
DTX-466	4/12/2019	Hemmo Pharmaceuticals Private Limited Certificate of Analysis: 2-D-TYR Vasopressin (Powder Synthetic) (Batch No. VK-IMP-2-D-Tyr-010718)	EAGLEVAS0051077	EAGLEVAS0051083	801, 802
DTX-467	4/12/2019	Hemmo Pharmaceuticals Private Limited Certificate of Analysis: 8-Orn-Vasopressin (Powder Synthetic) (Batch No. VK-IMP-8-Orn-010516)	EAGLEVAS0051084	EAGLEVAS0051089	801, 802
DTX-468	4/12/2019	Hemmo Pharmaceuticals Private Limited Certificate of Analysis: Des-Pro-Vasopressin (Powder Synthetic) (Batch No. VK-IMP-DES-PRO-010516)	EAGLEVAS0051090	EAGLEVAS0051095	801, 802
DTX-469	4/21/2018	Hemmo Pharmaceuticals Private Limited Certificate of Analysis: Vasopressin Parallel Dimer (Powder Synthetic) (Batch No. VK-IMP-PD-020117)	EAGLEVAS0051096	EAGLEVAS0051096	801, 802
DTX-470	5/7/2019	Hemmo Pharmaceuticals Private Limited Certificate of Analysis: Trisulfide Vasopressin (Synthetic) (Batch No. VK-IMP-SULF-020219)	EAGLEVAS0051097	EAGLEVAS0051103	801, 802
DTX-471		Eagle Pharmaceuticals ANDA Module: 3.2.S.7.1 Stability Summary and Conclusions (Vasopressin, USP) - Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0051108	EAGLEVAS0051108	801, 802
DTX-472		Par Pharmaceutical, Inc. Sales Training Document: <i>Vasopressin Q&A for Training Purposes</i>	PAR-VASO_0014732	PAR-VASO_0014734	401, 402, 403, 801-802
DTX-473	10/15/2015	Email from M. Kenney to K. Ziemba et al. re Vasopressin Impurities	PAR-VASO_0018216	PAR-VASO_0018217	
DTX-474	1/22/2016	Email from M. Kenney to K. Ziemba re Vasopressin leachables for 10 mL Vasopressin	PAR-VASO_0019062	PAR-VASO_0019063	
DTX-475	1/18/2012	JHP Pharmaceuticals, LLC Draft Memorandum from M. Bergren to B. Boesch et al. re Specifications and Rationale for Pitressin (20 U/mL) Made under Batch Card 2002132	PAR-VASO_0022274	PAR-VASO_0022281	401, 402, 403, 801, 802
DTX-476	9/21/2011	Email from M. Joyce to G. Vasquez and M. Kenney re Pitressin	PAR-VASO_0022283	PAR-VASO_0022286	
DTX-477		JHP Pharmaceuticals NDA Module: 3.2.P.2.6 Compatibility - Pitressin® (NDA No. 204485)	PAR-VASO_0072739	PAR-VASO_0072739	401, 402, 403
DTX-478	6/26/2012	JHP Pharmaceuticals, LLC Product Development Report (No. DEV-12-033R): <i>Comparison Report of Stability Results for Competitor Vasopressin Products</i>	PAR-VASO_0072780	PAR-VASO_0072790	

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DTX-479	1/27/2012	JHP Pharmaceuticals, LLC Master Batch Record: SV 4200 Pitressin (Synthetic), 20 Units per 1 mL (Batch No. 310573-1) (Revision Code: 001)	PAR-VASO_0073678	PAR-VASO_0073723	
DTX-480	1/27/2012	JHP Pharmaceuticals, LLC Master Batch Record: SV 4200 Pitressin (Synthetic), 20 Units per 1 mL (Batch No. 310573F) (Revision Code: 001)	PAR-VASO_0073724	PAR-VASO_0073772	
DTX-481	1/23/2013	JHP Pharmaceuticals, LLC Product Development Report (No. DEV-13-005R): <i>Report on the Results of a Stability Study Pitressin Use and Dilution with Saline</i>	PAR-VASO_0078383	PAR-VASO_0078389	
DTX-482		JHP Pharmaceuticals, LLC Stability Tables: <i>Pitressin Registration Stability Tables through 12 Mos</i>	PAR-VASO_0078390	PAR-VASO_0078410	
DTX-483	6/28/2012	JHP Pharmaceuticals, LLC Stability Protocol Report: <i>Pitressin 20 Units/mL, Stock Number 2002132 Demonstration/Registration Stability Protocol</i> (Version: 2.0)	PAR-VASO_0078411	PAR-VASO_0078413	401, 402, 403
DTX-484	11/15/2013	JHP Pharmaceuticals, LLC Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use (Form FDA 356h): Vasopressin Injection, USP (NDA No. 204485)	PAR-VASO_0078490	PAR-VASO_0078493	401, 402, 403
DTX-485	11/15/2013	JHP Pharmaceuticals, LLC Request to the FDA for Reconsideration of Proprietary Name: Vasostrict® (Vasopressin Injection, USP), Synthetic (NDA No. 204485)	PAR-VASO_0078494	PAR-VASO_0078501	401, 402, 403
DTX-486		Vasostrict® (Vasopressin Injection, USP) Synthetic Package Labeling	PAR-VASO_0078505	PAR-VASO_0078505	106
DTX-487	11/15/2013	Letter from G. Vasquez of JHP Pharmaceuticals, LLC to Dr. N. Stockbridge of the FDA re NDA Amendment: Proprietary Name Request; NDA 204485, SN 0018; Vasostrict® (vasopressin injection, USP) Synthetic	PAR-VASO_0078506	PAR-VASO_0078506	401, 402, 403
DTX-488		Vasostrict® (Vasopressin Injection, USP) Synthetic Package Labeling	PAR-VASO_0078507	PAR-VASO_0078507	
DTX-489	12/20/2013	FDA Submission Receipt	PAR-VASO_0078582	PAR-VASO_0078582	901, 902
DTX-490	12/20/2013	JHP Pharmaceuticals, LLC Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use (Form FDA 356h): Vasopressin Injection, USP (NDA No. 204485)	PAR-VASO_0078586	PAR-VASO_0078589	
DTX-491	12/20/2013	Letter from G. Vasquez of JHP Pharmaceuticals, LLC to Dr. N. Stockbridge of the FDA re Pitressin® (vasopressin injection, USP) Synthetic NDA #204485, S/N 0018; Responses to Complete Response Letter Received July 19, 2013	PAR-VASO_0078590	PAR-VASO_0078590	106, 1003, 401, 402, 403
DTX-492		VasoStrict® (vasopressin injection) Prescribing Information	PAR-VASO_0078594	PAR-VASO_0078601	901, 902
DTX-493	12/2013	JHP Pharmaceuticals, LLC Study Plan Report: <i>Postmarketing Pediatric Study Plan (PSP) Vasostrict: NDA 204485</i>	PAR-VASO_0078602	PAR-VASO_0078610	401, 402, 403
DTX-494	8/16/2016	Tabulated Stability Data through 9-Month Interval: Vasostrict® (vasopressin injection USP), 20 units/mL, 10mL vial	PAR-VASO_0090002	PAR-VASO_0090014	
DTX-495	7/21/2016	Email from C. English to A. Adams et al. re NDA 204485 Vasostrict - FDA Complete Response Letter	PAR-VASO_0090015	PAR-VASO_0090015	106, 1003

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DTX-496	7/21/2016	Complete Response Letter from Dr. R. Raghavachari of the FDA to C. English of Par Sterile Products, LLC re NDA No. 204485	PAR-VASO_0090016	PAR-VASO_0090018	801, 802
DTX-497	7/21/2016	Email from M. Kenney to V. Kannan re vasostrict 12 mo analysis	PAR-VASO_0090019	PAR-VASO_0090019	
DTX-498	7/20/2016	Email from M. Kenney to V. Kannan re 12 month single dose stability test.jpg	PAR-VASO_0090020	PAR-VASO_0090021	106, 1003
DTX-499		Tabulated Stability Data through 9-Month Interval: Vasostrict® (vasopressin injection USP), 20 units/mL, 10 mL vial	PAR-VASO_0090022	PAR-VASO_0090034	106, 1003, 901, 902
DTX-500	2/24/2016	Par Pharmaceutical, Inc. Product Development Technical Report (No. FRD-16-001): <i>Vasostrict, 20 Units/mL, pH 3.8 Acetate Buffer, Multiple Dose (Stock #2002525)</i>	PAR-VASO_0093747	PAR-VASO_0093783	
DTX-501		Parke-Davis Product Validation Report: SV 4200 Pitressin (Synthetic), 10 units/ml, 0.5ml (Stock Nos. 4200A904, 4200A954)	PAR-VASO_0094865	PAR-VASO_0094932	401, 402, 403, 801, 802, 901, 902
DTX-502	4/16/2012	JHP Pharmaceuticals, LLC Product Development Technical Report (No. DEV-12-016): <i>Identification of Pitressin Impurities and Development of the AVP Impurity Marker Solution D009-19</i>	PAR-VASO_0106801	PAR-VASO_0106829	
DTX-503		Par Pharmaceutical, Inc. Presentation: <i>Vasopressin Experimental Summary</i>	PAR-VASO_0192148	PAR-VASO_0192181	
DTX-504	3/16/2009	JHP Pharmaceuticals, LLC Research Report (No. 703-00159): <i>Analytical Method Validation Report for the Determination of Vasopressin and Impurities in Pitressin by Gradient HPLC</i>	PAR-VASO_0025902	PAR-VASO_0025949	
DTX-505	9/29/2015	Par Pharmaceutical, Inc. Product Development Technical Report (No. FRD-16-001): <i>Vasostrict, 20 Units/mL, pH 3.8 Acetate Buffer, Single Dose (Stock # 2002501)</i>	PAR-VASO_0030399	PAR-VASO_0030458	
DTX-506		Email from M. Rennwald to S. Tetteh et al. re Vasostrict lot 788445	PAR-VASO_0050127	PAR-VASO_0050128	401, 402, 403
DTX-507	6/10/2016	Email from A. Kremkow to S. Tetteh et al. re Vasostrict lot 788445	PAR-VASO_0050130	PAR-VASO_0050131	401, 402, 403
DTX-508	6/14/2016	Email from S. Mikolajczak to J. Zebelian re Vasostrict APR status for completion-Stability/Reserves	PAR-VASO_0050133	PAR-VASO_0050133	401, 402, 403
DTX-509	6/14/2016	Email from S. Mikolajczak to A. Kremkow et al. re Vasostrict lot 788445	PAR-VASO_0050135	PAR-VASO_0050135	401, 402, 403
DTX-510	6/14/2016	Email from J. Zebelian to S. Mikolajczak re Vasostrict APR status for completion-Stability/Reserves	PAR-VASO_0050137	PAR-VASO_0050137	401, 402, 403
DTX-511	6/14/2016	Email from A. Kremkow to S. Mikolajczak et al. re Vasostrict lot 788445	PAR-VASO_0050139	PAR-VASO_0050140	401, 402, 403
DTX-512	6/5/2016	Email from S. Mikolajczak to A. Kremkow et al. re Schedule for this week	PAR-VASO_0050142	PAR-VASO_0050142	401, 402, 403
DTX-513		Par Pharmaceutical, Inc. Task Agenda: <i>QC - Stability/Sample Center: Schedule for Week of 6/06/16</i>	PAR-VASO_0050143	PAR-VASO_0050143	401, 402, 403
DTX-514	6/12/2016	Email from S. Mikolajczak to A. Kremkow et al. re Schedule for this week	PAR-VASO_0050145	PAR-VASO_0050145	401, 402, 403
DTX-515	7/14/2016	Email from J. Harneck to T. Toureau re Stability Lot Review	PAR-VASO_0050148	PAR-VASO_0050148	401, 402, 403
DTX-516	7/14/2016	Email from M. Rennwald to J. Harneck et al. re Stability Lot Review	PAR-VASO_0050149	PAR-VASO_0050152	401, 402, 403
DTX-517	7/14/2016	Email from M. Rennwald to T. Toureau re Stability Lot Review	PAR-VASO_0050153	PAR-VASO_0050153	401, 402, 403
DTX-518	7/15/2016	Email from S. Mikolajczak to A. Kremkow, et al. re Inactivated Studies??	PAR-VASO_0050154	PAR-VASO_0050154	401, 402, 403

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DTX-519	5/1/2017	Email from S. Mikolajczak to A. Velez re NDA 204485; Vasostrict (vasopressin injection, USP) Annual Report Document Request	PAR-VASO_0050156	PAR-VASO_0050157	401, 402, 403
DTX-520	5/1/2017	Email from S. Mikolajczak to L. Kennedy, et al. re Initial data needed for upcoming Vasostrict Annual Report	PAR-VASO_0050158	PAR-VASO_0050158	401, 402, 403
DTX-521	5/1/2017	Email from S. Mikolajczak C. English et al. re Vasostrict description spec update- CC PR 24282	PAR-VASO_0050160	PAR-VASO_0050160	401, 402, 403
DTX-522	8/29/2017	Moved to Joint Exhibit List (JTX-2)	PAR-VASO_0295216	PAR-VASO_0295298	
DTX-523	5/1/2017	Email from M. Rennwald to C. English et al. re Vasostrict description spec update- CC PR 24282	PAR-VASO_0050162	PAR-VASO_0050163	401, 402, 403
DTX-524		Par Pharmaceutical, Inc. Lab Notebook (No. 44) of Vinayagam Loannan Regarding Vasostrict (Issued: Jan. 27, 2015)	PAR-VASO_0059897	PAR-VASO_0059949	
DTX-525	2/17/2016	Par Pharmaceutical, Inc. Product Development Technical Report (No. FRD 16-001): <i>Vasostrict, 20 Units/mL, pH 3.8 Acetate Buffer, Multiple Dose (Stock # 2002501)</i>	PAR-VASO_0060127	PAR-VASO_0060163	ID
DTX-526		Spreadsheet: Vasostrict® Reformulation Impurities Data	PAR-VASO_0061004	PAR-VASO_0061004	
DTX-527		Spreadsheet: Vasopressin Samples Impurities Data	PAR-VASO_0061005	PAR-VASO_0061005	
DTX-528	2/5/2016	Par Sterile Products, LLC Master Batch Record: Vasostrict™, 20 Units per 1 mL (Stock No. 2002132) (Revision Code: 010)	PAR-VASO_0066728	PAR-VASO_0066823	
DTX-529	4/16/2012	JHP Pharmaceuticals Product Development Technical Report (No. DEV-12-016), <i>Identification of Pitressin Impurities and Development of the AVP Impurity Marker Solution D009-19</i>	PAR-VASO_0088184	PAR-VASO_0088212	
DTX-530	6/18/2015	Par Sterile Products, LLC Master Batch Record: Vasosrtrict™, 20 Units per 1 mL (Revision Code: 009)	PAR-VASO_0100543	PAR-VASO_0100638	
DTX-531	8/6/2008	JHP Pharmaceuticals, LLP Memorandum from D. Battisti to J. Gantenbein et al. re Vasopressin Information and Items for Discussion	PAR-VASO_0108374	PAR-VASO_0108387	106, 901, 902, 1003, multiple separate documents
DTX-532	6/11/2012	JHP Pharmaceuticals, LLP Memorandum from M. Bergren to B. Boesch et al. re Specifications and Rationale for Pitressin (20 U/mL), 1 mL Made under Batch Card 2002132	PAR-VASO_0120046	PAR-VASO_0120057	401, 402, 403
DTX-533		Meeting Minutes: Compilation of Minutes for Specifications Committee Meetings dated January 10, 2012 through July 18, 2013	PAR-VASO_0120395	PAR-VASO_0120491	106, 401, 402, 403, 901, 902, 1003, multiple separate documents
DTX-534	6/17/2016	Par Pharmaceutical, Inc. Presentation: <i>Technical Operations Par Sterile Products</i>	PAR-VASO_0129974	PAR-VASO_0130027	401, 402, 403
DTX-535	1/27/2012	JHP Pharmaceuticals, LLC Master Batch Record: SV 4200 Pitressin (Synthetic), 20 Units per 1 mL (Revision Code: 001)	PAR-VASO_0190426	PAR-VASO_0190427	106, 1003
DTX-536	6/26/2014	JHP Pharmaceuticals, LLC Master Batch Record: Vasostrict™, 20 Units per 1 mL (Revision Code: 003)	PAR-VASO_0190433	PAR-VASO_0190435	106, 1003, multiple separate documents
DTX-537		Parkedale Pharmaceuticals Product Validation Addendum: Pitressin (Synthetic) USP Bulk Solution, 20 Units per 1mL (Stock No. AMP 4200: 4200X912)	PAR-VASO_0202061	PAR-VASO_0202095	401, 402, 403, 801, 802
DTX-538		Spreadsheet: Pitressin Study Design Notes & Impurities Data	PAR-VASO_0226936	PAR-VASO_0227034	
DTX-539		Spreadsheet: 4-Week Study Assay (%LC) and Total Impurities (%) Data	PAR-VASO_0241227	PAR-VASO_0241227	

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DTX-540		Spreadsheet: 4-Week Study Assay (%LC) and Total Impurities (%) Data	PAR-VASO_0241229	PAR-VASO_0241229	
DTX-541	10/8/2019	Plaintiff Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC's First Supplemental Response to Defendant Eagle Pharmaceuticals Inc.'s Invalidity Contentions			401, 402, 403, 801, 802, AA, Legal
DTX-542	3/31/2016	Declaration under 37 C.F.R. § 1.132 by Inventor Vinayagam Kannan, in re Application of: Matthew Kenney (U.S. Patent Appl. No. 14/717,882)	PAR-VASO-0002580	PAR-VASO-0002590	401, 402, 403
DTX-543	5/22/2017	Declaration under 37 C.F.R. § 1.132 by Inventor Vinayagam Kannan, in re Application of: Matthew Kenney (U.S. Patent Appl. No. 14/717,877)	PAR-VASO-0008804	PAR-VASO-0008824	
DTX-544	8/11/2015	Declaration under 37 C.F.R. § 1.132 by Inventor Sunil Vandse, in re Application of: Matthew Kenney (U.S. Patent Appl. No. 14/717,882)	PAR-VASO-0001039	PAR-VASO-0001046	401, 402, 403
DTX-545	1/22/2016	Declaration under 37 C.F.R. § 1.132 by Inventor Sunil Vandse, in re Application of: Matthew Kenney (U.S. Patent Appl. No. 14/717,882)	PAR-VASO-0002304	PAR-VASO-0002317	401, 402, 403
DTX-546	11/24/2015	Declaration under 37 C.F.R. § 1.130(a) by Inventor Vinayagam Kannan, in re Application of: Matthew Kenney (U.S. Patent Appl. No. 14/717,877)			
DTX-547	11/24/2015	Declaration under 37 C.F.R. § 1.130(a) by Michelle Bonomi-Huvala, in re Application of: Matthew Kenney (U.S. Patent Appl. No. 14/717,877)			
DTX-548	11/2010	U.S. Food & Drug Admin., <i>Guidance for Industry: ANDAs: Impurities in Drug Products</i> (Nov. 2010)			801, 802
DTX-549	6/2006	U.S. Food & Drug Admin., <i>Guidance for Industry: Q3B(R2) Impurities in New Drug Products</i> (July 2006)			801, 802
DTX-550	9/9/2013	Expert Report of Lee Kirsch, Ph.D, dated Sept. 9, 2013, <i>Helsinn Healthcare S. A. and Roche Palo Alto LLC, v. Dr. Reddy's Laboratories, LTD., et al.</i> , C.A. Nos. 11-3962, 11-5579 (MLC)(DEA), Helsinn Healthcare Exhibit 2027, (Trial PGR2016-00008)			401, 402, 403, 801, 802
DTX-551	6/5/2015	Trial Transcript, dated June 5, 2015, <i>Helsinn Healthcare S. A. and Roche Palo Alto LLC, v. Dr. Reddy's Laboratories, LTD., et al.</i> , C.A. No. 11-3962 (MLC)(DEA)			401, 402, 403, 801, 802
DTX-552	1/31/2020	Plaintiff's Supplemental Claim Construction Response Brief, <i>Par Pharmaceutical, Inc., et al. v. Sandoz Inc.</i> , C.A. No. 18-cv-14895-BRM-DEA (D.I. 88, D.Del.)			401, 402, 403, 801, 802, AA, Legal
DTX-553	7/27/2016	Complaint and Demand for Jury Trial, <i>Fresenius Kabi USA, LLC v. Par Sterile Products, LLC, and Par Pharmaceutical Companies, Inc.</i> , C.A. No. 16-4544 (D.I. 1, D.N.J.)			401, 402, 403, 801, 802, AA, Legal
DTX-554	3/3/2020	Joint Claim Construction Brief, <i>Par Pharmaceutical, Inc., et al., v. Amphastar Pharmaceuticals, Inc.</i> , C.A. No. 18-2032-CFC (D.I. 93, D.Del.)			401, 402, 403, 801, 802, AA, Legal

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DTX-555	12/12/2014	Declaration of Lee Kirsch, Ph.D. In Support of Defendant's Claim Construction Brief, dated Dec. 15, 2015, <i>Astrazeneca Pharmaceuticals LP, et al., v. Teva Pharmaceuticals USA, Inc.</i> , C.A. No. 14-1478-GMS			402, 403, 801, 802
DTX-556	4/26/1999	Lithuanian Patent No. LT 4487 B to Gendrolis et al.			401, 402, 403, 701, 702, 801, 802, 901, 902, PMIL
DTX-557		Anjali B. Joshi et al., <i>The Degradation Pathways of Glucagon in Acidic Solutions</i> , 203 Int'l J. Pharm. 115 (2000)			801, 802,
DTX-558		Anjali B. Joshi & Lee E. Kirsch, <i>The Estimation of Glutaminyol Deamidation and Aspartyl Cleavage Rates in Glucagon</i> , 273 Int'l J. Pharm. 213 (2004)			801, 802, L
DTX-559		Anjali B. Joshi et al., <i>Studies on the Mechanism of Aspartic Acid Cleavage and Glutamine Deamidation in the Acidic Degradation of Glucagon</i> , 94(9) J. Pharm. Scis. 1912 (2005)			801, 802, L
DTX-560		Ravi Gupta et al., <i>The FDA Unapproved Drugs Initiative: An Observational Study of the Consequences for Drug Prices and Shortages in the United States</i> , 23(10) J. Manag. Care & Spec. Pharm. (JMCP) 1066 (2017)			401, 402, 403, 801, 802, 901, 902, L
DTX-561	4/5/2017	Mark L. Baum, <i>How FDA Rules Made a \$15 Drug Cost \$400</i> , Wall Street J. (Apr. 5, 2017)			401, 402, 403, 801, 802, 901, 902, L
DTX-562	11/1/2018	Kaylene Barrera et al., <i>Drug Shortages: The Invisible Epidemic</i> , The Bulletin (Nov. 1, 2018)			401, 402, 403, 801, 802, 901, 902, L
DTX-563	8/2/2019	Albany Molecular Research Inc. Standard Operating Procedure Report (No. STA-IPX-0153): <i>Vasopressin Injections, USP, In Process Test Procedure</i> (Revision: 03)	AMRIVAS0114139	AMRIVAS0114161	401, 402, 403, 801, 802
DTX-564	12/31/2014	Par Pharmaceutical Companies, Inc. Annual Report (Form 10-K) for Fiscal Year Ended Dec. 31, 2014			401, 402, 403, 801, 802, 901, 902, L
DTX-565	3/31/2015	Par Pharmaceutical Companies, Inc. Quarterly Report (Form 10-Q) for Quarterly Period Ended Mar. 31, 2015			401, 402, 403, L
DTX-566	6/30/2015	Par Pharmaceutical Companies, Inc. Quarterly Report (Form 10-Q) for Quarterly Period Ended June 30, 2015			401, 402, 403, L
DTX-567	12/31/2015	Endo International PLC Annual Report (Form 10-K) for Fiscal Year Ended Dec. 31, 2015			401, 402, 403, L
DTX-568	12/31/2016	Endo International PLC Annual Report (Form 10-K) for Fiscal Year Ended Dec. 31, 2016			401, 402, 403, L
DTX-569	12/31/2017	Endo International PLC Annual Report (Form 10-K) for Fiscal Year Ended Dec. 31, 2017			401, 402, 403, L
DTX-570	12/31/2018	Endo International PLC Annual Report (Form 10-K) for Fiscal Year Ended Dec. 31, 2018			401, 402, 403, L
DTX-571	12/31/2019	Endo International PLC Annual Report (Form 10-K) for Fiscal Year Ended Dec. 31, 2019			401, 402, 403, L
DTX-572	6/1/2006	<i>ICH Topic Q 3 B (R2) Impurities in New Drug Products: Note for Guidance (CPMP/ICH/2738/99)</i> , EMEA June 2006			801, 802, 901, 902, L

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DTX-573	8/1/2019	AMRI Vasopressin Injection USP Project #: PD SVA-07, Storage Condition: 5C Inverted - Lot Number: SVA007.5I	AMRIVAS0117114	AMRIVAS0117117	401, 402, 403, 801, 802, L
DTX-574	8/1/2019	AMRI Vasopressin Injection USP Project #: PD SVA-07, Storage Condition: 25C/60%RH Inverted - Lot Number: SVA007.25I	AMRIVAS0117110	AMRIVAS0117113	401, 402, 403, 801, 802, L
DTX-575	8/1/2019	AMRI Vasopressin Injection USP Project #: PD SVA-07, Storage Condition: 5C Inverted - Lot Number: SVA008.5I	AMRIVAS0117124	AMRIVAS0117127	401, 402, 403, 801, 802, L
DTX-576	8/1/2019	AMRI Vasopressin Injection USP Project #: PD SVA-07, Storage Condition: 25C/60%RH Inverted - Lot Number: SVA008.25I	AMRIVAS0117120	AMRIVAS0117123	401, 402, 403, 801, 802, L
DTX-577	9/10/2019	AMRI Vasopressin Injection USP Project #: PD SVA-07, Storage Condition: 5C Inverted - Lot Number: SVA009.5I	AMRIVAS0117134	AMRIVAS0117137	401, 402, 403, 801, 802, L
DTX-578	9/10/2019	AMRI Vasopressin Injection USP Project #: PD SVA-07, Storage Condition: 25C/60%RH Inverted - Lot Number: SVA009.25I	AMRIVAS0117130	AMRIVAS0117133	401, 402, 403, 801, 802, L
DTX-579	6/17/2013	OSOBIO Project Notebook Document Number: STA-PJN-0029, SVA007/008 - 6M, Ver. 3	AMRIVAS0117118	AMRIVAS0117119	401, 402, 403, 801, 802, L
DTX-580	6/17/2013	OSOBIO Project Notebook Document Number: STA-PJN-0029, SVA009.6M, Ver. 3	AMRIVAS0117128	AMRIVAS0117129	401, 402, 403, 801, 802, L
DTX-581	6/17/2013	OSOBIO Project Notebook Document Number: STA-PJN-0029, SVA007/8 - 1M, Ver. 3	AMRIVAS0117100	AMRIVAS0117100	401, 402, 403, 801, 802, L
DTX-582	6/17/2013	OSOBIO Project Notebook Document Number: STA-PJN-0029, SVA004.6M, Ver. 3	AMRIVAS0117101	AMRIVAS0117102	401, 402, 403, 801, 802, L
DTX-583	6/17/2013	OSOBIO Project Notebook Document Number: STA-PJN-0029, SVA009 - 1M, Ver. 3	AMRIVAS0117103	AMRIVAS0117104	401, 402, 403, 801, 802, L
DTX-584	6/17/2013	OSOBIO Project Notebook Document Number: STA-PJN-0029, SVA007/8 - 3M, Ver. 3	AMRIVAS0117105	AMRIVAS0117106	401, 402, 403, 801, 802, L
DTX-585	6/17/2013	OSOBIO Project Notebook Document Number: STA-PJN-0029, SVA009.2M, Ver. 3	AMRIVAS0117107	AMRIVAS0117107	401, 402, 403, 801, 802, L
DTX-586	6/17/2013	OSOBIO Project Notebook Document Number: STA-PJN-0029, SVA009.3M, Ver. 3	AMRIVAS0117108	AMRIVAS0117109	401, 402, 403, 801, 802, L
DTX-587	6/27/2017	Moved to Joint Exhibit List (JTX-1)	PAR-VASO_0295299	PAR-VASO_0295377	
DTX-588	9/5/2017	Moved to Joint Exhibit List (JTX-3)	PAR-VASO_0295378	PAR-VASO_0295459	
DTX-589	1/29/2020	Affidavit of Jasmina Marinkovic of American Regent, Inc. re American Regent's Production of Documents Bearing Bates Numbers AR3-VASO-0000001 - AR3-VASO-0000022 in Response to Eagle Pharmaceuticals Inc.'s Subpoena <i>Duces Tecum</i> , dated October 3, 2019			602, LOF, 801, 802
DTX-590	1/19/2020	OSO BioPharmaceuticals Manufacturing, LLC Laboratory Notebook Excerpts Regarding Vasopressin Injection, USP Samples SVA005/006 - 9M (Document No. STA-PJN-0029) (Version: 3.0)	AMRIVAS0117138	AMRIVAS0117139	401, 402, 403, 801, 802, L
DTX-591	1/20/2020	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Conditions: 5C Inverted, 5C Upright) (Lot Nos. SVA004.5I, SVA004.5U)	AMRIVAS0117140	AMRIVAS0117143	401, 402, 403, 801, 802, L
DTX-592	1/20/2020	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Conditions: 25C/60% RH Inverted, 25C/60% RH Upright) (Lot Nos. SVA004.25I, SVA004.25U)	AMRIVAS0117144	AMRIVAS0117147	401, 402, 403, 801, 802, L

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DTX-593	1/20/2020	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Condition: 30C/65% RH Inverted) (Lot No. SVA004.30I)	AMRIVAS0117148	AMRIVAS0117149	401, 402, 403, 801, 802, L
DTX-594	1/7/2020	OSO BioPharmaceuticals Manufacturing, LLC Laboratory Notebook Excerpts Regarding Vasopressin Injection, USP Sample SVA004.9M (Document No. STA-PJN-0029) (Version: 3.0)	AMRIVAS0117150	AMRIVAS0117151	401, 402, 403, 801, 802, L
DTX-595	1/22/2020	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Conditions: 5C Inverted, 5C Upright) (Lot Nos. SVA005.5I, SVA005.5U)	AMRIVAS0117152	AMRIVAS0117155	401, 402, 403, 801, 802, L
DTX-596	1/22/2020	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Conditions: 25C/60% RH Inverted, 25C/60% RH Upright) (Lot Nos. SVA005.25I, SVA005.25U)	AMRIVAS0117156	AMRIVAS0117159	401, 402, 403, 801, 802, L
DTX-597	1/22/2020	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Condition: 30C/65% RH Inverted) (Lot No. SVA005.30I)	AMRIVAS0117160	AMRIVAS0117161	401, 402, 403, 801, 802, L
DTX-598	1/22/2020	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Conditions: 5C Inverted, 5C Upright) (Lot Nos. SVA006.5I, SVA006.5U)	AMRIVAS0117162	AMRIVAS0117165	401, 402, 403, 801, 802, L
DTX-599	1/22/2020	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Conditions: 25C/60% RH Inverted, 25C/60% RH Upright) (Lot Nos. SVA006.25I, SVA006.25U)	AMRIVAS0117166	AMRIVAS0117169	401, 402, 403, 801, 802, L
DTX-600	1/22/2020	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Condition: 30C/65% RH Inverted) (Lot No. SVA006.30I)	AMRIVAS0117170	AMRIVAS0117171	401, 402, 403, 801, 802, L
DTX-601	4/2/2020	OSO BioPharmaceuticals Manufacturing, LLC Laboratory Notebook Excerpts Regarding Vasopressin Injection, USP Sample SVA004.12M (Document No. STA-PJN-0029) (Version: 3.0)	AMRIVAS0117172	AMRIVAS0117173	401, 402, 403, 801, 802, L
DTX-602	6/17/2013	OSO BioPharmaceuticals Manufacturing, LLC Laboratory Notebook Excerpts Regarding Vasopressin Injection, USP Sample SVA005/6.12M (Document No. STA-PJN-0029) (Version: 3.0)	AMRIVAS0117174	AMRIVAS0117175	401, 402, 403, 801, 802, L
DTX-603	6/17/2013	OSO BioPharmaceuticals Manufacturing, LLC Laboratory Notebook Excerpts Regarding Vasopressin Injection, USP Sample SVA005/7/8.9M (Document No. STA-PJN-0029) (Version: 3.0)	AMRIVAS0117176	AMRIVAS0117177	401, 402, 403, 801, 802, L
DTX-604	6/28/2016	Certified Copy of U.S. Patent No. 9,375,478 to Kenney et al.	EAGLEVAS0058407	EAGLEVAS0058441	401, 402, 403
DTX-605	8/29/2017	Certified Copy of U.S. Patent No. 9,744,239 to Kenney et al.	EAGLEVAS0058442	EAGLEVAS0058478	401, 402, 403
DTX-606	4/10/2018	Certified Copy of U.S. Patent No. 9,937,223 to Kenney et al.	EAGLEVAS0058479	EAGLEVAS0058587	401, 402, 403
DTX-607	4/1/2020	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Condition: 25C/60% RH Inverted) (Lot No. SVA04A.25I)	AMRIVAS0117178	AMRIVAS0117181	401, 402, 403, 801, 802, L
DTX-608	8/1/2019	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Condition: 5H Inverted -(Lot No. SVA007.5I)	AMRIVAS0117182	AMRIVAS0117185	401, 402, 403, 801, 802, L

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DTX-609	8/1/2019	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Condition: 25C/60% RH Inverted) (Lot No. SVA007.25I)	AMRIVAS0117186	AMRIVAS0117189	401, 402, 403, 801, 802, L
DTX-610	8/1/2019	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Condition: 5C Inverted - (Lot No. SVA008.5I)	AMRIVAS0117190	AMRIVAS0117193	401, 402, 403, 801, 802, L
DTX-611	8/1/2019	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Condition: 25C/60% RH Inverted) (Lot No. SVA008.25I)	AMRIVAS0117194	AMRIVAS0117197	401, 402, 403, 801, 802, L
DTX-612	4/12/2018	Letter from B. Patel on behalf of the FDA to R. Ashworth on behalf of Eagle re Paragraph IV Acknowledgement ANDA Receipt	EAGLEVAS0000013	EAGLEVAS0000018	401, 402, 403, 801, 802, L
DTX-613	6/17/2013	OSO BioPharmaceuticals Manufacturing, LLC Laboratory Notebook Excerpts Regarding SVA005/6A-1M (Ver. 3)	AMRIVAS0117198	AMRIVAS0117199	401, 402, 403, 801, 802, L
DTX-614	6/17/2013	OSO BioPharmaceuticals Manufacturing, LLC Laboratory Notebook Excerpts Regarding SVA004A.2M (Ver. 3)	AMRIVAS0117200	AMRIVAS0117201	401, 402, 403, 801, 802, L
DTX-615	6/17/2013	OSO BioPharmaceuticals Manufacturing, LLC Laboratory Notebook Excerpts Regarding SVA009.9M (Ver. 3)	AMRIVAS0117202	AMRIVAS0117203	401, 402, 403, 801, 802, L
DTX-616	6/17/2013	OSO BioPharmaceuticals Manufacturing, LLC Laboratory Notebook Excerpts Regarding SVA005/006A.2M (Ver. 3)	AMRIVAS0117204	AMRIVAS0117205	401, 402, 403, 801, 802, L
DTX-617	5/18/2000	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL, 1.16 ML/vial (Storage Condition: 25C/60% RH Inverted) (Lot No. SVA004.25I)	AMRIVAS0117206	AMRIVAS0117209	401, 402, 403, 801, 802, L
DTX-618	6/2/2020	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL, 1.16 ML/vial (Storage Condition: 25C/60% RH Inverted) (Lot No. SVA004A.25I)	AMRIVAS0117210	AMRIVAS0117213	401, 402, 403, 801, 802, L
DTX-619	7/8/2020	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL, 1.16 ML/vial (Storage Condition: 25C/60% RH Inverted) (Lot No. SVA004A.25I)	AMRIVAS0117214	AMRIVAS0117217	401, 402, 403, 801, 802, L
DTX-620	6/17/2013	OSO BioPharmaceuticals Manufacturing, LLC Laboratory Notebook Excerpts Regarding SVA004A.3M (Ver. 3)	AMRIVAS0117218	AMRIVAS0117218	401, 402, 403, 801, 802, L
DTX-621	6/17/2013	OSO BioPharmaceuticals Manufacturing, LLC Laboratory Notebook Excerpts Regarding SVA005/6A-1M (Ver. 3)	AMRIVAS0117219	AMRIVAS0117220	401, 402, 403, 801, 802, L
DTX-622	6/1/2020	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL, 1.16 ML/vial (Storage Condition: 25C/60% RH Inverted) (Lot No. SVA005.25I)	AMRIVAS0117221	AMRIVAS0117224	401, 402, 403, 801, 802, L
DTX-623	5/18/2020	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL, 1.16 ML/vial (Storage Condition: 30C/65% RH Inverted) (Lot No. SVA005.30I)	AMRIVAS0117225	AMRIVAS0117226	401, 402, 403, 801, 802, L
DTX-624	5/18/2020	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL, 1.16 ML/vial (Storage Condition: 5C Inverted) (Lot No. SVA005.5I)	AMRIVAS0117227	AMRIVAS0117230	401, 402, 403, 801, 802, L
DTX-625	4/17/2020	SGS Certificate of Analysis for Vasopressin Injection 0.0377mg/ML, Lot: SVA005.25I (25C/60% Inverted) - 12 month	AMRIVAS0117231	AMRIVAS0117277	401, 402, 403, 801, 802, L

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DTX-626	5/21/2020	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL, 1.16 ML/vial (Storage Condition: 25C/60% RH Upright) (Lot No. SVA005A.25I)	AMRIVAS0117278	AMRIVAS0117281	401, 402, 403, 801, 802, L
DTX-627	7/23/2020	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL, 1.16 ML/vial (Storage Condition: 25C/60% RH Inverted) (Lot No. SVA005A.25I)	AMRIVAS0117282	AMRIVAS0117285	401, 402, 403, 801, 802, L
DTX-628	5/18/2020	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL, 1.16 ML/vial (Storage Condition: 25C/60% RH Inverted) (Lot No. SVA005A.25I)	AMRIVAS0117286	AMRIVAS0117289	401, 402, 403, 801, 802, L
DTX-629	6/1/2020	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL, 1.16 ML/vial (Storage Condition: 25C/60% RH Inverted) (Lot No. SVA006A.25I)	AMRIVAS0117290	AMRIVAS0117293	401, 402, 403, 801, 802, L
DTX-630	5/18/2020	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL, 1.16 ML/vial (Storage Condition: 30C/65% RH Inverted) (Lot No. SVA006.30I)	AMRIVAS0117294	AMRIVAS0117295	401, 402, 403, 801, 802, L
DTX-631	5/18/2020	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL, 1.16 ML/vial (Storage Condition: 5C Inverted) (Lot No. SVA006.5I)	AMRIVAS0117296	AMRIVAS0117299	401, 402, 403, 801, 802, L
DTX-632	5/21/2020	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL, 1.16 ML/vial (Storage Condition: 25C/60%RH Inverted) (Lot No. SVA006A.25I)	AMRIVAS0117300	AMRIVAS0117303	401, 402, 403, 801, 802, L
DTX-633	7/23/2020	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL, 1.16 ML/vial (Storage Condition: 25C/60%RH Inverted) (Lot No. SVA006A.25I)	AMRIVAS0117304	AMRIVAS0117307	401, 402, 403, 801, 802, L
DTX-634	7/23/2020	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL, 1.16 ML/vial (Storage Condition: 25C/60%RH Inverted) (Lot No. SVA006A.25I)	AMRIVAS0117308	AMRIVAS0117311	401, 402, 403, 801, 802, L
DTX-635	5/18/2020	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL, 1.16 ML/vial (Storage Condition: 25C/60%RH Inverted) (Lot No. SVA006A.25I)	AMRIVAS0117312	AMRIVAS0117315	401, 402, 403, 801, 802, L
DTX-636	6/17/2013	OSO BioPharmaceuticals Manufacturing, LLC Laboratory Notebook Excerpts Regarding SVA007/8.9M (Ver. 3)	AMRIVAS0117316	AMRIVAS0117317	401, 402, 403, 801, 802, L
DTX-637	6/17/2020	OSO BioPharmaceuticals Manufacturing, LLC Laboratory Notebook Excerpts Regarding SVA007/8.12M (Ver. 3)	AMRIVAS0117318	AMRIVAS0117319	401, 402, 403, 801, 802, L
DTX-638		Table of Item Numbers, Serial Numbers, and Quantities	PAR-VASO-0297181	PAR-VASO-0297181	
DTX-639	Aug-20	Vasopressin Injection Label, Revised 8/2020	EAGLEVAS0058665	EAGLEVAS0058671	801, 802, L
DTX-640	2007	Skoog, et al, Principles of Instrumental Analysis, 6th Ed., pg 683-685 (2007)	EAGLEVAS0059107	EAGLEVAS0059111	801, 802, L
DTX-641	2015	Seltman, Experimental Design and Analysis (2015)	EAGLEVAS0058672	EAGLEVAS0059099	801, 802, L
DTX-642	Oct-77	Hahn, The Hazards of Extrapolation in Regression Analysis, Jour. of Qual. Techn, Vol. 9, No. 4 (1977)	EAGLEVAS0059100	EAGLEVAS0059106	801, 802, L
DTX-643	Aug-20	Letter from FDA to American Regent re NDA Approval for NDA 212593	EAGLEVAS0058661	EAGLEVAS0058664	401, 402, 403, 801, 802, L

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DTX-644	9/4/2020	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Conditions: 25C/60% RH Inverted, 25C/60% RH Upright) (Lot Nos. SVA007.25I, SVA007.25U)	AMRIVAS0117320	AMRIVAS0117323	401, 402, 403, 801, 802, L
DTX-645	9/4/2020	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Conditions: 5C Inverted, 5C Upright) (Lot Nos. SVA007.5I, SVA007.5U)	AMRIVAS0117324	AMRIVAS0117327	401, 402, 403, 801, 802, L
DTX-646	9/13/2020	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Conditions: 25C/60% RH Inverted, 25C/60% RH Upright) (Lot Nos. SVA007A.25I, SVA007A.25U)	AMRIVAS0117328	AMRIVAS0117331	401, 402, 403, 801, 802, L
DTX-647	9/4/2020	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Conditions: 25C/60% RH Inverted, 25C/60% RH Upright) (Lot Nos. SVA007A.25I, SVA007A.25U)	AMRIVAS0117332	AMRIVAS0117335	401, 402, 403, 801, 802, L
DTX-648	9/8/2020	OSO BioPharmaceuticals Manufacturing, LLC Laboratory Notebook Excerpts Regarding Vasopressin Injection, USP Sample SVA007A/8A.1M (Document No. STA-PJN-0029) (Version: 3.0)	AMRIVAS0117336	AMRIVAS0117337	401, 402, 403, 801, 802, L
DTX-649	9/4/2020	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Conditions: 25C/60% RH Inverted, 25C/60% RH Upright) (Lot Nos. SVA008.25I, SVA008.25U)	AMRIVAS0117338	AMRIVAS0117341	401, 402, 403, 801, 802, L
DTX-650	9/4/2020	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Conditions: 5C Inverted, 5C Upright) (Lot Nos. SVA008.5I, SVA008.5U)	AMRIVAS0117342	AMRIVAS0117345	401, 402, 403, 801, 802, L
DTX-651	9/13/2020	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Conditions: 25C/60% RH Inverted, 25C/60% RH Upright) (Lot Nos. SVA008A.25I, SVA008A.25U)	AMRIVAS0117346	AMRIVAS0117349	401, 402, 403, 801, 802, L
DTX-652	9/4/2020	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Conditions: 25C/60% RH Inverted, 25C/60% RH Upright) (Lot Nos. SVA008A.25I, SVA008A.25U)	AMRIVAS0117350	AMRIVAS0117353	401, 402, 403, 801, 802, L
DTX-653	9/9/2020	OSO BioPharmaceuticals Manufacturing, LLC Laboratory Notebook Excerpts Regarding Vasopressin Injection, USP Sample SVA009.12M (Document No. STA-PJN-0029) (Version: 3.0)	AMRIVAS0117354	AMRIVAS0117355	401, 402, 403, 801, 802, L
DTX-654	7/28/2020	Email from J. Picurro of Eagle Pharmaceuticals, Inc. to P. Orlaku of the FDA re ANDA 211538 - Vasopressin Injection, USP, Post-Complete Response Meeting Follow-up Inquiry	EAGLEVAS0059112	EAGLEVAS0059115	401, 402, 403, 801, 802, L
DTX-655	8/28/2020	FDA Response Letter from C. Flotildes of the FDA to J. Picurro of Eagle Pharmaceuticals, Inc. re ANDA No. 211538	EAGLEVAS0059116	EAGLEVAS0059119	401, 402, 403, 801, 802, L
DTX-656	7/30/2020	Follow-Up Inquiry from J. Picurro of Eagle Pharmaceuticals, Inc. to the FDA re Post-Complete Response Letter Teleconference Meeting dated July 27, 2020, and Enclosures Thereto	EAGLEVAS0059120	EAGLEVAS0059139	401, 402, 403, 801, 802, L

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DTX-657	8/4/2020	Email from P. Orlaku of the FDA to J. Picurro of Eagle Pharmaceuticals, Inc. re RE: ANDA 211538 - Vasopressin Injection, USP, Post-Complete Response Meeting Follow-up Inquiry	EAGLEVAS0059140	EAGLEVAS0059144	401, 402, 403, 801, 802, L
DTX-658	8/4/2020	Email from J. Picurro of Eagle Pharmaceuticals, Inc. to S. Vehovic of the FDA re RE: Eagle Pharm / Janis Picurro --FW: ANDA 211538/Missed Goal Data	EAGLEVAS0059145	EAGLEVAS0059147	401, 402, 403, 801, 802, L
DTX-659		VASOPRESSIN Injection, 20 Units per mL, Package Labeling for Carton (Black & White Version)	EAGLEVAS0059152	EAGLEVAS0059152	401, 402, 403, 801, 802, L
DTX-660		Package Labeling Table: Explanation of Package Labeling Differences between the Revised and Older Versions of the Vasopressin Injection Vial and Carton	EAGLEVAS0059153	EAGLEVAS0059156	401, 402, 403, 801, 802, L
DTX-661		VASOPRESSIN Injection, 20 Units per mL, Package Labeling for Vial (Black & White Version)	EAGLEVAS0059157	EAGLEVAS0059157	401, 402, 403, 801, 802, L
DTX-662	9/2020	VASOPRESSIN Injection Prescribing Information (revised: 09/ 2020)	EAGLEVAS0059158	EAGLEVAS0059166	401, 402, 403, 801, 802, L
DTX-663		Redline of VASOPRESSIN Injection Prescribing Information (revised: 09/ 2020) against VASOPRESSIN Injection Prescribing Information (revised: 09/ 2019)	EAGLEVAS0059167	EAGLEVAS0059169	401, 402, 403, 801, 802, L
DTX-664		VASOPRESSIN Injection, 20 Units per mL, Package Labeling for Carton (Color Version)	EAGLEVAS0059172	EAGLEVAS0059172	401, 402, 403, 801, 802, L
DTX-665		VASOPRESSIN Injection, 20 Units per mL, Package Labeling for Vial (Color Version)	EAGLEVAS0059173	EAGLEVAS0059173	401, 402, 403, 801, 802, L
DTX-666		RLD Comparison Table: Explanation of Differences between Eagle Pharmaceuticals, Inc.'s Proposed ANDA Product and Reference Listed Drug	EAGLEVAS0059174	EAGLEVAS0059188	401, 402, 403, 801, 802, L
DTX-667		RLD Comparison Table: Explanation of Differences between Eagle Pharmaceuticals, Inc.'s Proposed ANDA Product and Reference Listed Drug	EAGLEVAS0059189	EAGLEVAS0059203	401, 402, 403, 801, 802, L
DTX-668	4/2020	VASOSTRICT® (vasopressin injection) Prescribing Information (revised: 04/2020)	EAGLEVAS0059204	EAGLEVAS0059213	401, 402, 403, 801, 802, L
DTX-669	2/2020	VASOSTRICT® (vasopressin injection) Prescribing Information (revised: 02/2020)	EAGLEVAS0059214	EAGLEVAS0059221	401, 402, 403, 801, 802, L
DTX-670		Eagle Pharmaceuticals, Inc. Application to Market a New or Abbreviated New Drug or Biologic for Human Use (Form FDA 356h): Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0059222	EAGLEVAS0059230	401, 402, 403, 801, 802, L
DTX-671	9/24/2020	Major Complete Response Amendment Letter from J. Picurro of Eagle Pharmaceuticals Inc. to the FDA re ANDA No. 211538, and Enclosures Thereto	EAGLEVAS0059231	EAGLEVAS0059262	401, 402, 403, 801, 802, L
DTX-672		Eagle Pharmaceuticals ANDA Module: 2 Supplement: Question-Based Review for Drug Product: Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0059266	EAGLEVAS0059398	401, 402, 403, 801, 802, L
DTX-673		Eagle Pharmaceuticals ANDA Module: 2.3.S Drug Substance - Quality Overall Summary: Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0059399	EAGLEVAS0059447	401, 402, 403, 801, 802, L

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DTX-674		Eagle Pharmaceuticals ANDA Module: 3.2.P.2 Pharmaceutical Development: Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0059660	EAGLEVAS0059660	401, 402, 403, 801, 802, L
DTX-675		Eagle Pharmaceuticals ANDA Module: 3.2.P.3.4 Controls of Critical Steps and Intermediates: Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0059734	EAGLEVAS0059749	401, 402, 403, 801, 802, L
DTX-676		Eagle Pharmaceuticals ANDA Module: 3.2.P.3.1 Manufacturers: Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0059750	EAGLEVAS0059751	401, 402, 403, 801, 802, L
DTX-677	9/12/2020	Albany Molecular Research Inc. Standard Operating Procedure Report (No. STA-IPX-0153): <i>Vasopressin Injection, USP, In-Process Test Procedure</i> (Revision: 05)	EAGLEVAS0059752	EAGLEVAS0059777	401, 402, 403, 801, 802, L
DTX-678		Eagle Pharmaceuticals ANDA Module: 3.2.P.5.1 Specifications: Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0059778	EAGLEVAS0059781	401, 402, 403, 801, 802, L
DTX-679		Eagle Pharmaceuticals ANDA Module: 3.2.P.5.2 Analytical Procedures: Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0059782	EAGLEVAS0059783	401, 402, 403, 801, 802, L
DTX-680	9/12/2020	Albany Molecular Research Inc. Standard Operating Procedure Report (No. STA-IPX-0119): <i>Vasopressin Injection, USP, End Product Test Procedure</i> (Revision: 07)	EAGLEVAS0059796	EAGLEVAS0059832	401, 402, 403, 801, 802, L
DTX-681		Eagle Pharmaceuticals ANDA Module: 3.2.P.5.5 Characterization of Impurities: Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0059870	EAGLEVAS0059881	401, 402, 403, 801, 802, L
DTX-682		Eagle Pharmaceuticals ANDA Module: 3.2.P.5.6 Justification of Specifications: Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0059882	EAGLEVAS0059902	401, 402, 403, 801, 802, L
DTX-683		Eagle Pharmaceuticals ANDA Module: 3.2.P.8.2 Post-Approval Stability Protocol and Stability Commitment: Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0059929	EAGLEVAS0059932	401, 402, 403, 801, 802, L
DTX-684		Eagle Pharmaceuticals ANDA Module: 3.2.P.8.3 Stability Data: Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0059933	EAGLEVAS0059938	401, 402, 403, 801, 802, L
DTX-685		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2017 Registration Batch, Batch SVA001A Inverted Position, DOM: 03Mar2017: 25°C/60% RH Stability Data after 21 Months Storage at 2-8°C, Stability Protocol PD SVA-02 Rev02, Stability Start: 19Dec2018</i>	EAGLEVAS0059939	EAGLEVAS0059939	401, 402, 403, 801, 802, L
DTX-686		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2017 Registration Batch, Batch SVA001A Upright Position, DOM: 03Mar2017: 25°C/60% RH Stability Data after 21 Months Storage at 2-8°C, Stability Protocol PD SVA-02 Rev02, Stability Start: 19Dec2018</i>	EAGLEVAS0059940	EAGLEVAS0059940	401, 402, 403, 801, 802, L
DTX-687		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2017 Registration Batch, Batch SVA002A Inverted Position, DOM: 07Mar2017: 25°C/60% RH Stability Data after 21 Months Storage at 2-8°C, Stability Protocol PD SVA-02 Rev02, Stability Start: 19Dec2018</i>	EAGLEVAS0059941	EAGLEVAS0059941	401, 402, 403, 801, 802, L

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DTX-688		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2017 Registration Batch, Batch SVA002A Upright Position, DOM: 07Mar2017: 25°C/60% RH Stability Data after 21 Months Storage at 2-8°C, Stability Protocol PD SVA-02 Rev02, Stability Start: 19Dec2018</i>	EAGLEVAS0059942	EAGLEVAS0059942	401, 402, 403, 801, 802, L
DTX-689		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2017 Registration Batch, Batch SVA003A Inverted Position, DOM: 10Mar2017: 25°C/60% RH Stability Data after 21 Months Storage at 2-8°C, Stability Protocol PD SVA-02 Rev02, Stability Start: 19Dec2018</i>	EAGLEVAS0059943	EAGLEVAS0059943	401, 402, 403, 801, 802, L
DTX-690		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2017 Registration Batch, Batch SVA003A Upright Position, DOM: 10Mar2017: 25°C/60% RH Stability Data after 21 Months Storage at 2-8°C, Stability Protocol PD SVA-02 Rev02, Stability Start: 19Dec2018</i>	EAGLEVAS0059944	EAGLEVAS0059944	401, 402, 403, 801, 802, L
DTX-691		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2019 Characterization Batch, Batch SVA004A Inverted Position, DOM: 15Mar2019: 12 Months 2-8°C Plus 12 Months 25°C/60% RH Stability Data, Stability Protocol PD SVA-04 Rev01, Stability Start: 02Apr2020</i>	EAGLEVAS0059945	EAGLEVAS0059945	401, 402, 403, 801, 802, L
DTX-692		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2019 Characterization Batch, Batch SVA004A Upright Position, DOM: 15Mar2019: 12 Months 2-8°C Plus 12 Months 25°C/60% RH Stability Data, Stability Protocol PD SVA-04 Rev01, Stability Start: 02Apr2020</i>	EAGLEVAS0059946	EAGLEVAS0059946	401, 402, 403, 801, 802, L
DTX-693		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2019 Characterization Batch, Batch SVA004 Inverted Position, DOM: 15Mar2019: 25°C/60% RH Stability Data, Stability Protocol PD SVA-04 Rev01, Stability Start: 02Apr2019</i>	EAGLEVAS0059947	EAGLEVAS0059947	401, 402, 403, 801, 802, L
DTX-694		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2019 Characterization Batch, Batch SVA004 Inverted Position, DOM: 15Mar2019: Long Term (2° to 8°C) Stability Data, Stability Protocol PD SVA-04 Rev01, Stability Start: 02Apr2019</i>	EAGLEVAS0059948	EAGLEVAS0059948	401, 402, 403, 801, 802, L
DTX-695		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2019 Characterization Batch, Batch SVA004 Inverted Position, DOM: 15Mar2019: Intermediate 30°C/65% RH Stability Data, Stability Protocol PD SVA-04 Rev01, Stability Start: 02Apr2019</i>	EAGLEVAS0059949	EAGLEVAS0059949	401, 402, 403, 801, 802, L
DTX-696		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2019 Characterization Batch, Batch SVA004 Inverted Position, DOM: 15Mar2019: Accelerated 40°C/75% RH Stability Data, Stability Protocol PD SVA-04 Rev01, Stability Start: 02Apr2019</i>	EAGLEVAS0059950	EAGLEVAS0059950	401, 402, 403, 801, 802, L

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DTX-697		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2019 Characterization Batch, Batch SVA004 Upright Position, DOM: 15Mar2019: 25°C/60% RH Stability Data, Stability Protocol PD SVA-04 Rev01, Stability Start: 02Apr2019</i>	EAGLEVAS0059951	EAGLEVAS0059951	401, 402, 403, 801, 802, L
DTX-698		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2019 Characterization Batch, Batch SVA004 Upright Position, DOM: 15Mar2019: Long Term (2° to 8°C) Stability Data, Stability Protocol PD SVA-04 Rev01, Stability Start: 02Apr2019</i>	EAGLEVAS0059952	EAGLEVAS0059952	401, 402, 403, 801, 802, L
DTX-699		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2019 Characterization Batch, Batch SVA005A Inverted Position, DOM: 03Apr2019: 12 Months 2-8°C Plus 12 Months 25°C/60% RH Stability Data, Stability Protocol PD SVA-04 Rev01, Stability Start: 17Apr2020</i>	EAGLEVAS0059953	EAGLEVAS0059953	401, 402, 403, 801, 802, L
DTX-700		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2019 Characterization Batch, Batch SVA005A Upright Position, DOM: 03Apr2019: 12 Months 2-8°C Plus 12 Months 25°C/60% RH Stability Data, Stability Protocol PD SVA-04 Rev01, Stability Start: 17Apr2020</i>	EAGLEVAS0059954	EAGLEVAS0059954	401, 402, 403, 801, 802, L
DTX-701		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2019 Characterization Batch, Batch SVA005 Inverted Position, DOM: 03Apr2019: 25°C/60% RH Stability Data, Stability Protocol PD SVA-04 Rev01, Stability Start: 17Apr2019</i>	EAGLEVAS0059955	EAGLEVAS0059955	401, 402, 403, 801, 802, L
DTX-702		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2019 Characterization Batch, Batch SVA005 Inverted Position, DOM: 03Apr2019: Long Term (2° to 8°C) Stability Data, Stability Protocol PD SVA-04 Rev01, Stability Start: 17Apr2019</i>	EAGLEVAS0059956	EAGLEVAS0059956	401, 402, 403, 801, 802, L
DTX-703		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2019 Characterization Batch, Batch SVA005 Inverted Position, DOM: 03Apr2019: Intermediate 30°C/65% RH Stability Data, Stability Protocol PD SVA-04 Rev01, Stability Start: 17Apr2019</i>	EAGLEVAS0059957	EAGLEVAS0059957	401, 402, 403, 801, 802, L
DTX-704		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2019 Characterization Batch, Batch SVA005 Inverted Position, DOM: 03Apr2019: Accelerated 40°C/75% RH Stability Data, Stability Protocol PD SVA-04 Rev01, Stability Start: 17Apr2019</i>	EAGLEVAS0059958	EAGLEVAS0059958	401, 402, 403, 801, 802, L
DTX-705		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2019 Characterization Batch, Batch SVA005 Upright Position, DOM: 03Apr2019: 25°C/60% RH Stability Data, Stability Protocol PD SVA-04 Rev01, Stability Start: 17Apr2019</i>	EAGLEVAS0059959	EAGLEVAS0059959	401, 402, 403, 801, 802, L

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PAR PHARMACEUTICAL, INC., et al. v. EAGLE PHARMACEUTICALS INC.
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EXHIBIT NO.	DATE	DESCRIPTION	BEG BATES NO.	END BATES NO.	OBJECTIONS
DTX-706		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2019 Characterization Batch, Batch SVA005 Upright Position, DOM: 03Apr2019: Long Term (2° to 8°C) Stability Data, Stability Protocol PD SVA-04 Rev01, Stability Start: 17Apr2019</i>	EAGLEVAS0059960	EAGLEVAS0059960	401, 402, 403, 801, 802, L
DTX-707		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2019 Characterization Batch, Batch SVA006A Inverted Position, DOM: 08Apr2019: 12 Months 2-8°C Plus 12 Months 25°C/60% RH Stability Data, Stability Protocol PD SVA-04 Rev01, Stability Start: 17Apr2020</i>	EAGLEVAS0059961	EAGLEVAS0059961	401, 402, 403, 801, 802, L
DTX-708		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2019 Characterization Batch, Batch SVA006A Upright Position, DOM: 08Apr2019: 12 Months 2-8°C Plus 12 Months 25°C/60% RH Stability Data, Stability Protocol PD SVA-04 Rev01, Stability Start: 17Apr2020</i>	EAGLEVAS0059962	EAGLEVAS0059962	401, 402, 403, 801, 802, L
DTX-709		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2019 Characterization Batch, Batch SVA006 Inverted Position, DOM: 08Apr2019: 25°C/60% RH Stability Data, Stability Protocol PD SVA-04 Rev01, Stability Start: 17Apr2019</i>	EAGLEVAS0059963	EAGLEVAS0059963	401, 402, 403, 801, 802, L
DTX-710		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2019 Characterization Batch, Batch SVA006 Inverted Position, DOM: 08Apr2019: Long Term (2° to 8°C) Stability Data, Stability Protocol PD SVA-04 Rev01, Stability Start: 17Apr2019</i>	EAGLEVAS0059964	EAGLEVAS0059964	401, 402, 403, 801, 802, L
DTX-711		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2019 Characterization Batch, Batch SVA006 Inverted Position, DOM: 08Apr2019: Intermediate 30°C/65% RH Stability Data, Stability Protocol PD SVA-04 Rev01, Stability Start: 17Apr2019</i>	EAGLEVAS0059965	EAGLEVAS0059965	401, 402, 403, 801, 802, L
DTX-712		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2019 Characterization Batch, Batch SVA006 Inverted Position, DOM: 08Apr2019: Accelerated 40°C/75% RH Stability Data, Stability Protocol PD SVA-04 Rev01, Stability Start: 17Apr2019</i>	EAGLEVAS0059966	EAGLEVAS0059966	401, 402, 403, 801, 802, L
DTX-713		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2019 Characterization Batch, Batch SVA006 Upright Position, DOM: 08Apr2019: 25°C/60% RH Stability Data, Stability Protocol PD SVA-04 Rev01, Stability Start: 17Apr2019</i>	EAGLEVAS0059967	EAGLEVAS0059967	401, 402, 403, 801, 802, L
DTX-714		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2019 Characterization Batch, Batch SVA006 Upright Position, DOM: 08Apr2019: Long Term (2° to 8°C) Stability Data, Stability Protocol PD SVA-04 Rev01, Stability Start: 17Apr2019</i>	EAGLEVAS0059968	EAGLEVAS0059968	401, 402, 403, 801, 802, L

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EXHIBIT NO.	DATE	DESCRIPTION	BEG BATES NO.	END BATES NO.	OBJECTIONS
DTX-715		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2019 Optimization Batch, Batch SVA007 Inverted Position, DOM: 07Jul2019: 25°C/60% RH Stability Data, Stability Protocol PD SVA-07 Rev00, Stability Start: 01Aug2019</i>	EAGLEVAS0059969	EAGLEVAS0059969	401, 402, 403, 801, 802, L
DTX-716		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2019 Optimization Batch, Batch SVA007 Inverted Position, DOM: 07Jul2019: Long Term (2° to 8°C) Stability Data, Stability Protocol PD SVA-07 Rev00, Stability Start: 01Aug2019</i>	EAGLEVAS0059970	EAGLEVAS0059970	401, 402, 403, 801, 802, L
DTX-717		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2019 Optimization Batch, Batch SVA007 Upright Position, DOM: 07Jul2019: 25°C/60% RH Stability Data, Stability Protocol PD SVA-07 Rev00, Stability Start: 01Aug2019</i>	EAGLEVAS0059971	EAGLEVAS0059971	401, 402, 403, 801, 802, L
DTX-718		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2019 Optimization Batch, Batch SVA007 Upright Position, DOM: 07Jul2019: Long Term (2° to 8°C) Stability Data, Stability Protocol PD SVA-07 Rev00, Stability Start: 01Aug2019</i>	EAGLEVAS0059972	EAGLEVAS0059972	401, 402, 403, 801, 802, L
DTX-719		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2019 Optimization Batch, Batch SVA008 Inverted Position, DOM: 16Jul2019: 25°C/60% RH Stability Data, Stability Protocol PD SVA-07 Rev00, Stability Start: 01Aug2019</i>	EAGLEVAS0059973	EAGLEVAS0059973	401, 402, 403, 801, 802, L
DTX-720		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2019 Optimization Batch, Batch SVA008 Inverted Position, DOM: 16Jul2019: Long Term (2° to 8°C) Stability Data, Stability Protocol PD SVA-07 Rev00, Stability Start: 01Aug2019</i>	EAGLEVAS0059974	EAGLEVAS0059974	401, 402, 403, 801, 802, L
DTX-721		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2019 Optimization Batch, Batch SVA008 Upright Position, DOM: 16Jul2019: 25°C/60% RH Stability Data, Stability Protocol PD SVA-07 Rev00, Stability Start: 01Aug2019</i>	EAGLEVAS0059975	EAGLEVAS0059975	401, 402, 403, 801, 802, L
DTX-722		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2019 Optimization Batch, Batch SVA008 Upright Position, DOM: 16Jul2019: Long Term (2° to 8°C) Stability Data, Stability Protocol PD SVA-07 Rev00, Stability Start: 01Aug2019</i>	EAGLEVAS0059976	EAGLEVAS0059976	401, 402, 403, 801, 802, L
DTX-723		Eagle Pharmaceuticals Inc. Stability Tables: <i>Vasopressin Injection, USP 0.0377 mg/mL, 2019 Optimization Batch, Batch SVA009 Inverted Position, DOM: 10Aug2019: 25°C/60% RH Stability Data, Stability Protocol PD SVA-07 Rev00, Stability Start: 10Sep2019</i>	EAGLEVAS0059977	EAGLEVAS0059977	401, 402, 403, 801, 802, L

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EXHIBIT NO.	DATE	DESCRIPTION	BEG BATES NO.	END BATES NO.	OBJECTIONS
DTX-724		Eagle Pharmaceuticals Inc. Stability Tables: Vasopressin Injection, USP 0.0377 mg/mL, 2019 Optimization Batch, Batch SVA009 Inverted Position, DOM: 10Aug2019: Long Term (2° to 8°C) Stability Data, Stability Protocol PD SVA-07 Rev00, Stability Start: 10Sep2019	EAGLEVAS0059978	EAGLEVAS0059978	401, 402, 403, 801, 802, L
DTX-725		Eagle Pharmaceuticals Inc. Stability Tables: Vasopressin Injection, USP 0.0377 mg/mL, 2019 Optimization Batch, Batch SVA009 Upright Position, DOM: 10Aug2019: 25°C/60% RH Stability Data, Stability Protocol PD SVA-07 Rev00, Stability Start: 10Sep2019	EAGLEVAS0059979	EAGLEVAS0059979	401, 402, 403, 801, 802, L
DTX-726		Eagle Pharmaceuticals Inc. Stability Tables: Vasopressin Injection, USP 0.0377 mg/mL, 2019 Optimization Batch, Batch SVA009 Upright Position, DOM: 10Aug2019: Long Term (2° to 8°C) Stability Data, Stability Protocol PD SVA-07 Rev00, Stability Start: 10Sep2019	EAGLEVAS0059980	EAGLEVAS0059980	401, 402, 403, 801, 802, L
DTX-727		Eagle Pharmaceuticals ANDA Module: 3.2.P.8.1 Stability Summary and Conclusion: Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0059986	EAGLEVAS0060015	401, 402, 403, 801, 802, L
DTX-728		Eagle Pharmaceuticals ANDA Module: 3.2.S.3.2 Impurities: Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0060135	EAGLEVAS0060153	401, 402, 403, 801, 802, L
DTX-729		Eagle Pharmaceuticals ANDA Module: 3.2.S.4.1 Specification: Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0060154	EAGLEVAS0060157	401, 402, 403, 801, 802, L
DTX-730		Eagle Pharmaceuticals ANDA Module: 3.2.S.4.5 Justification of Specification: Vasopressin Injection, USP (ANDA No. 211538)	EAGLEVAS0060298	EAGLEVAS0060306	401, 402, 403, 801, 802, L
DTX-731	9/26/2020	ANDA Amendment Acknowledgement Letter from P. Oriaku of the FDA to J. Picurro of Eagle Pharmaceuticals, Inc. re ANDA No. 211538	EAGLEVAS0060332	EAGLEVAS0060334	401, 402, 403, 801, 802, L
DTX-732	10/4/2020	Email from P. Oriaku of the FDA to J. Picurro of Eagle Pharmaceuticals, Inc. re ANDA 211538/Priority Review	EAGLEVAS0060336	EAGLEVAS0060336	401, 402, 403, 801, 802, L
DTX-733	10/5/2020	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Conditions: 5C Inverted, 5C Upright) (Lot Nos. SVA004.5I, SVA004.5U)	AMRIVAS0117356	AMRIVAS0117359	401, 402, 403, 801, 802, L
DTX-734	10/5/2020	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Conditions: 25C/60% RH Inverted, 25C/60% RH Upright) (Lot Nos. SVA004A.25I, SVA004A.25U)	AMRIVAS0117360	AMRIVAS0117363	401, 402, 403, 801, 802, L
DTX-735	10/1/2020	OSO BioPharmaceuticals Manufacturing, LLC Laboratory Notebook Regarding Vasopressin Injection, USP Sample SVA004 18M (Document No. STA-PJN-0029) (Version: 3.0)	AMRIVAS0117364	AMRIVAS0117365	401, 402, 403, 801, 802, L
DTX-736	10/5/2020	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Conditions: 25C/60% RH Inverted, 25C/60% RH Upright) (Lot Nos. SVA007A.25I, SVA007A.25U)	AMRIVAS0117366	AMRIVAS0117369	401, 402, 403, 801, 802, L
DTX-737	9/30/2020	OSO BioPharmaceuticals Manufacturing, LLC Laboratory Notebook Regarding Vasopressin Injection, USP Sample SVA007/8A.2M (Document No. STA-PJN-0029) (Version: 3.0)	AMRIVAS0117370	AMRIVAS0117371	401, 402, 403, 801, 802, L


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EXHIBIT NO.	DATE	DESCRIPTION	BEG BATES NO.	END BATES NO.	OBJECTIONS
DTX-738	10/5/2020	Albany Molecular Research Inc. Stability Tables: Vasopressin Injection, USP, 0.0377 mg/mL (Storage Conditions: 25C/60% RH Inverted, 25C/60% RH Upright) (Lot Nos. SVA008A.25I, SVA008A.25U)	AMRIVAS0117372	AMRIVAS0117375	401, 402, 403, 801, 802, L
DTX-739	10/9/2020	OSO BioPharmaceuticals Manufacturing, LLC Laboratory Notebook Regarding Vasopressin Injection, USP Sample SVA009A.1M (Document No. STA-PJN-0029) (Version: 3.0)	AMRIVAS0117376	AMRIVAS0117376	401, 402, 403, 801, 802, L
DTX-740	10/4/2020	Email from P. Oriaku re ANDA 211538 / Priority Review	EAGLEVAS0060337	EAGLEVAS0060337	401, 402, 403, 801, 802, L
DTX-741	10/16/2020	OSO Bio General Notebook Pages for SVA005/6.18M, Doc. No. STA-PJN-0029, Ver. 3, pgs 4-5	AMRIVAS0117377	AMRIVAS0117378	401, 402, 403, 801, 802, L
DTX-742	7/16/2020	OSO Bio General Notebook Pages for SVA005/6A.3M, Doc. No. STA-PJN-0029, Ver. 3, pgs 4-5	AMRIVAS0117379	AMRIVAS0117380	401, 402, 403, 801, 802, L
DTX-743	11/4/2020	OSO Bio General Notebook Pages for SVA007A/8A.3M, Doc. No. STA-PJN-0029, Ver. 3, pgs 6-7	AMRIVAS0117381	AMRIVAS0117382	401, 402, 403, 801, 802, L
DTX-744	11/9/2020	OSO Bio General Notebook Pages for SVA009A.2M, Doc. No. STA-PJN-0029, Ver. 3, pgs 4-5	AMRIVAS0117383	AMRIVAS0117384	401, 402, 403, 801, 802, L
DTX-745	11/20/2020	Alex M. Azar II, "Termination of the Food and Drug Administration's Unapproved Drugs Initiative; Request for Information Regarding Drugs Potentially Generally Recognized as Safe and Effective", Federal Register 2020, Vol. 65(228): 75331-34			401, 402, 403, 701, 702, 801, 802, L
DTX-746		Table Summaries of pH Data for Batches SVA001-009			401, 402, 403, 801, 802, 1006, L
DTX-747	12/9/2020	OSO Bio General Notebook Pages for SVA009A.3M, Doc. No. STA-PJN-0029, Ver. 3, p. 4	AMRIVAS0117385	AMRIVAS0117385	401, 402, 403, 801, 802, L
DTX-748	12/11/2020	Supplemental Validity Expert Report of L. Kirsch, dated December 11, 2020			
DTX-749	3/17/2020	Email from B. Goldberg to A. Cade et al., re Narrowed List of Asserted Claims			401, 402, 801-802, AA, L
DTX-1028	2013	Michael J. Akers & Michael R. DeFelippis, "Peptides and Proteins as Parenteral Solutions," in PHARMACEUTICAL FORMULATION DEVELOPMENT OF PEPTIDES AND PROTEINS pp. 149-192 (Lars Hovgaard et al., eds, 2nd ed. 2013)	AMPHPA0006136	AMPHPA0006184	
DTX-1039	2015	U.S. Pharmacopeia, <i>Vasopressin</i> , in 3 The National Formulary 5752 (2015)	AMPHPA0006744	AMPHPA0006747	

Par's Objection Key	
Code	Objection
106	partial document/lacks context (FRE 106)
401/402	lacks relevance (FRE 401/402)
403	unduly prejudicial/confusing/waste of time (FRE 403)
501/502	Privilege/Work Product (FRE 501/502)
602/LOF	lacks foundation/speculative (FRE 602)
701/702	improper opinion (FRE 701/702)
801-802	hearsay (FRE 802)
901/902	lacks authenticity (FRE 901/902)
1002	original document required (FRE 1002)
1003	incomplete/illegible (FRE 1003)
1006	improper summary (FRE 1006)
ID	insufficient/incorrect description
L	late/not produced
AA	attorney argument improperly offered as evidence; contains counsel colloquy or objections
C	compound
Legal	calls for a legal conclusion
Leading	leading question of a non-hostile witness
MC	Mischaracterizes/misstates witness's testimony
NR	nonresponsive
PMIL	Subject of pending motion in limine
P	privilege
OS	beyond the scope
V	Vague and/or ambiguous

EXHIBIT 9

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

<p>PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC and ENDO PAR INNOVATION COMPANY, LLC,</p> <p>Plaintiffs,</p> <p>v.</p> <p>EAGLE PHARMACEUTICALS INC.,</p> <p>Defendant.</p>	<p>C.A. No. 18-cv-823-CFC</p> <p></p>
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PLAINTIFFS' WITNESS LIST

Pursuant to Local Rule 16.3(c), Plaintiffs expect to call the following witnesses to testify live or by deposition at trial. Plaintiffs reserve the right to revise or supplement this list consistent with the Pretrial Order or as otherwise permitted by the Court. If any witness Plaintiffs intend to call to testify live is unavailable, Plaintiffs reserve the right to offer deposition testimony from such witness. Plaintiffs also reserve the right to call live or by deposition anyone appearing on Defendant's witness list. Plaintiffs further reserve the right to call live or by deposition any witness to provide foundational testimony should any party contest the authenticity or admissibility of any material proffered at trial. Plaintiffs reserve the right to call any witness for impeachment purposes. Finally, Plaintiffs reserve the right to call live or by deposition any fact witness designated by Defendants in their List of Witnesses that Defendants

elect not to call at trial. Plaintiffs are not required to present testimony from any witness on its list of witnesses.

WILL CALL LIST

<u>EXPERT WITNESS</u>	<u>LIVE OR BY DEPOSITION</u>
Lee Kirsch (CV included as Attachment A hereto)	Live
Zlatan Coralic (CV included as Attachment B hereto)	Live
Robert Minkin (CV included as Attachment C hereto)	Live

MAY CALL LIST

<u>WITNESS</u>	<u>LIVE OR BY DEPOSITION</u>
Domenic Ciarico	Live
Carla English	Live
Vinay Kannan	Live or by deposition
Suketu Sanghvi	Live
Ronald Aungst	Live or by deposition
Linda Dell	Live or by deposition
Adrian Hepner	Live or by deposition
James Romito	Live or by deposition
Stephen (Nate) Woltering	Live or by deposition

ATTACHMENT A

Lee E. Kirsch

Professor Emeritus

Department of Pharmaceutical Science Experimental Therapeutics

The University of Iowa

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Email: lee-kirsch@uiowa.edu

EDUCATION AND PROFESSIONAL HISTORY

Education

Ph D, Pharmaceutics, 1982
The Ohio State University

BS, Pharmacy, 1975
Purdue University

Professional and Academic Positions

Professor Emeritus, The University Iowa, January 2019 – present, Division of Pharmaceutics and Translational Therapeutics

Professor, The University of Iowa, August 2010 – December 2018, Division of Pharmaceutics (Primary Appointment), Department of Chemical and Biochemical Engineering (Secondary Appointment)

Visiting Professor, Mahidol Univesity, Faculty of Pharmacy, Thailand (January, 2014 – April, 2014)

Professor, Virginia Commonwealth University, Department of Pharmaceutics (Affiliate Appointment). (May 2005 - December 2018).

Adjunct Professor, Pharmaceutical Technology, Faculty of Pharmaceutical Sciences, Chulalongkorn University, Thailand (2003 – 2018)

Associate Professor, The University of Iowa, College of Pharmacy. (November 1994 - July 2010).

Associate Professor, The University of Iowa, Department of Chemical and Biochemical Engineering (Secondary Appointment). (May 2006 - July 2010).

Senior Research Scientist/group leader, Lilly Research Laboratories. (January 1992 - November 1994).

Research Scientist/group leader, Lilly Research Laboratories. (January 1987 - January 1992).

Senior Pharmaceutical Chemist, Lilly Research Laboratories. (November 1982 - January 1987).

Research Associate, The Ohio State University. (June 1979 - November 1982).

Teaching Assistant, The Ohio State University. (August 1978 - June 1979).

Community Pharmacist, Family Pharmacy North Bloomington, Indiana. (July 1975 - August 1978).

Honors and Recognition

Editor-in-chief, AAPS PharmSciTech Journal. (July 2008 – December, 2014).
Fellow of the American Association of Pharmaceutical Scientists (June 2013)
Distinguished Service Award, Parenteral Drug Association. (February 2011).
Editor, PDA Journal of Pharmaceutical Science and Technology. (July 2000 - June 2008).
Fred Simon Award for best paper, PDA Journal of Pharmaceutical Science and Technology.
(October 1997).
Jack L. Beal Postbaccalaureate Award, The Ohio State University College of Pharmacy. (May
1997).

TEACHING AT THE UNIVERSITY OF IOWA AND EXTERNAL TEACHING: INTERNATIONAL AND US

Professional PharmD Courses

Macromolecular Drug Substance, PHAR 8136, 2015-2017
Solution Drug Products, PHAR 8137, 2015
Regulatory and Quality Systems, PHAR 8137, 2015
Pharmacokinetics, PHAR 8112, 2015
Pharmacokinetics and Biopharmaceutics, Pharmacy 46:138, 2002-2009
Pharmaceutical Proteins unit in Pharmacy 46:123, 2002-2013
Advanced Compounding, Pharmacy 46:120, 2004-2005
Drug Stability in Pharmacy 46:123 and 46:124, 2005-2013, 1995-2000
PHAR 8136, 2016-2017
Fundamentals of Kinetics in Pharmacy 46:123, 46:050, 2005-2013
Fundamentals of Pharmacokinetics in Pharmacy 46:124, 2010-2013
Solids processing, Packaging, Capsules, Lyophilized Powders units in Pharmacy 46:124, 1995-
2000

Graduate Courses in Pharmaceutics

Pharmacy Research, Pharmacy 46:233, 1995-2017
Pharmaceutical Product Development, Pharmacy 46: 225, 1999 and 2006
Drug Degradation Kinetics and Mechanisms (Drug Stability) 46:206, 1995, 1997, 1999, 2001,
2003, 2007, 2009, 2011, 2013, 2015, 2017
Stability of Pharmaceuticals, PHAR 6701, 2015

External Teaching: International and US

Pharmaceutical Technology, Federal University of Rio Grande do Norte, Natal, Brazil, 2015
International Pharmaceutical Technology, University of the Philippines (Manila), 2015
Pharmaceutical Package Integrity, PDA Research and Training Center, 1998
Drug Degradation Kinetics Short Course, Chulalongkorn University, International Pharmaceutical
Technology Graduate Program, 2002, 2003, 2005, 2008-2016
Bangkok, Thailand
Drug Degradation Kinetics Short Course, Virginia Commonwealth University, Pharmaceutical
Sciences Graduate Program, 2005
Drug Degradation Kinetics Short Course, Mahidol University, Bangkok, Pharmaceutical Sciences
Graduate Program, 2014

M.S. Students Directed

Craig Moeckly (Non-thesis) degree conferred 1997
Walaisiri Muangsiri (Thesis) degree conferred July, 2000
Simei Li (Non-thesis) degree conferred December, 2000
Bhanu Kalvakota (Non-thesis) degree conferred December, 2002
Pipat Sittisak (Thesis) with W. Muangsiri, Chulalongkorn University, degree conferred 2010

Ph.D. Students Directed

Young-Sihn Sihn, degree conferred June 1997
Lida Nguyen, degree conferred December, 2001
Xiaoguang Zhang, degree conferred December, 2001
Anjali Joshi, degree conferred December, 2001
Walasiri Muangsiri, degree conferred December, 2003
Madhushree Gokhale, degree conferred May, 2006
Himanshu Naik (with L. Fleckenstein), degree conferred December, 2007
Boontarika Chanvorachote (with W. Muangsiri), degree conferred June, 2009 (Chulalongkorn University)
Salil Desai degree conferred December, 2009
Zhixin Zong degree conferred May, 2012
Jiang Qui, degree conferred May, 2013
Hong Guann Lee (with D. Flanagan), degree conferred May, 2015
Nguyen Quynh Hoa, degree conferred December, 2014
Radaduen Tinmanee, thesis defended May, 2015, anticipated graduation December, 2015
Mo'tasem Mohamed Alsmadi (with L. Fleckenstein), degree conferred December, 2014
Phawanan Sawangchan, degree conferred December, 2017
Pratak Ngeacharernkul degree conferred December, 2017
Éverton do Nascimento Alencar, visiting Ph.D. scholar from Federal University of Rio Grande do Norte, Natal, Brazil, 2014-2015, degree conferred December, 2017
Francisco Alexandrino Junior, visiting Ph.D. scholar from Federal University of Rio Grande do Norte, Natal, Brazil, 2016-2018
Silvana Cartaxo Da Costa Urtiga, visiting Ph.D. scholar from Federal University of Rio Grande do Norte, Natal, Brazil, 2017-2018

Post-doctoral Scholars

Gisela N. Piccirilli, Ph.D., 2011
Stephen Stamatis, Ph.D., 2011-2013
Eiji Ueyama, Ph.D., 2013-2014

SCHOLARSHIP/RESEARCH/PROFESSIONAL PRODUCTIVITY

Publications

1. Pratak Ngeacharernkul, Stephen D. Stamatis, Lee E. Kirsch (2018), Particle size distribution equivalency as novel predictors for bioequivalence, *AAPS PharmSciTech*, 19(7):2787-2800.
2. Stephen D. Stamatis, Lee E. Kirsch (2018), Using Manufacturing Design Space Concepts for Stability Risk Assessment—Gabapentin NIPTE/FDA Case Study, *AAPS PharmSciTech*,

- 19(7):2801-2807.
3. Stephen D. Stamatis, Linas Mockus, Lee E. Kirsch, Gintaras V. Reklaitis (2018) Chapter 5- Bayesian hierarchical modeling of gabapentin absorption and disposition with application to dosing regimen assessment, *Computer Aided Chemical Engineering*, **42**: 111-137.
4. Radaduen Tinmanee, Stephen D. Stamatis, Eji Ueyama, Kenneth R. Morris, Lee E. Kirsch (2018) Polymorphic and Covalent Transformations of Gabapentin in Binary Excipient Mixtures after Milling-Induced Stress, *Pharmaceutical Research*, **35**:39
5. Radaduen Tinmanee, Sarah C. Larsen, Kenneth R. Morris, Lee E. Kirsch (2017) Quantification of gabapentin polymorphs in gabapentin/excipient mixtures using solid state ¹³C NMR spectroscopy and X-ray powder diffraction, *Journal of Pharmaceutical and Biomedical Analysis*, **146**: 29-36.
6. Salil Dileep Desai and Lee E. Kirsch The Ortho Effect on the Acidic and Alkaline Hydrolysis of Substituted Formanilides, (2015) *International Journal of Chemical Kinetics*, **47**(8), 471-488.
7. Hoa Q. Nguyen, Stephen D. Stamatis, Lee E. Kirsch, (2015) A novel method for assessing drug degradation product safety using physiologically-based pharmacokinetic models and stochastic risk assessment, *Journal of Pharmaceutical Science*, **104**(9), 3101-3199.
8. Boontarika Chanvorachote, Jiang Qiu, Walaisiri Muangsiri, Ubonthip Nimmannit, and Lee E. Kirsch (2015) The interaction mechanism between lipopeptide (daptomycin) and polyamidoamine (PAMAM) dendrimers, *Journal of Peptide Science*, **21**: 312-319, 2015.
9. Qiu, J. and Kirsch, Lee E. (2014) Evaluation of Lipopeptide (Daptomycin) Aggregation Using Fluorescence, Light Scattering, and Nuclear Magnetic Resonance Spectroscopy, *Journal of Pharmaceutical Sciences*, **103**(3), 853–861.
5. Dempah KE, Barich DH, Kaushal AM, Zong Z, Desai SD, Suryanarayanan R.; Kirsch L, Munson EJ; (2013) Investigation Gabapentin Polymorphism Using Solid-State NMR Spectroscopy; *AAPS PharmSciTech*, **14**(1), 19-28.
6. Zong, Z., Qiu, J., Tinamnee, R., Kirsch, L. E. (2012). Kinetic model for solid-state degradation of gabapentin. *Journal of Pharmaceutical Science*, **101**(6), 2123-2133.
7. Zong, Z., Kirsch, L. E. (2012). Studies on the Instability of Chlorhexidine, Part 1. *Journal of Pharmaceutical Science*, **101**(7), 2417-2427.
8. Mockus, L., Lainez, J., Reklaitis, G., Kirsch, L. E. (2011). A Bayesian Approach to Pharmaceutical Product Quality Risk Quantification. *Informatica*, **22**(4), 537-558.
9. Qiu, J., Yu, L., Kirsch, L. E. (2011). Estimated pKa values for specific amino acid residues in daptomycin. *Journal of Pharmaceutical Science*, **100**(10), 4225-4233.
10. Ratcliff, J. L., Kirsch, L. E., Dykstra, J. W., Cooley, W. E. (2011). Fluoride and chlorine dioxide-containing compositions and method for reducing demineralization of teeth. *PCT Int. Appl*, WO 2010075419 A1 20100701.
11. Zong, Z., Desai, S., Barich, A., Huang, H.-S., Munson, E., Suryanarayanan, R., Kirsch, L. E. (2011). The Stabilizing Effect of Moisture on the Solid-State Degradation of Gabapentin. *AAPS PharmSciTech*, **12**(3), 924-931.
12. Chanvorachote, B., Nimmannit, U., Muangsiri, W., Kirsch, L. E. (2009). An Evaluation of a Fluorometric Method for Determining Binding Parameters of Drug–Carrier Complexes Using Mathematical Models Based on Total Drug Concentration. *Journal of Fluorescence*, **19**(4), 747-753.
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- Population Pharmacokinetics of Artesunate and Dihydroartemisinin Following Single- and Multiple-Dosing of Oral Artesunate in Healthy Subjects. *Malaria Journal*, **8**(1), 304.
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 16. Gokhale, M., Kirsch, L. E. (2009). Glycosylation of aromatic amines III: Mechanistic implications of the pH-dependent glycosylation of various aromatic amines (kynurenine, 2'-aminoacetophenone, daptomycin, and sulfamethoxazole). *Journal of Pharmaceutical Science*, DOI 10.1002/jps.21765.
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 28. Joshi, A., Kirsch, L. E. (2004). The estimation of glutaminy deamidation and aspartyl cleavage rates in glucagon. *International Journal of Pharmaceutics*, **273**(1-2), 213-219.
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- Glass Vials. *PDA Journal of Pharmaceutical Science and Technology*, **51**(5), 203.
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Presentations

1. Lee E. Kirsch, "Particle Size Distribution Overlap Metrics for the Evaluation of Disperse System Drug Product Equivalency", April 30, 2015, NIPTE/FDA Research Conference: Pharmaceutical Critical Path Manufacturing-2015, Rockville, MD
2. Lee Kirsch, Pharmaceutical Technology Lecture Series I at United Laboratories, Manila, Philippines, October 1, 2015 "Quality-by-Design", "Quality Risk Management", "Manufacturing Biopharmaceuticals"
3. Lee Kirsch, Pharmaceutical Technology Lecture Series II at United Laboratories, Manila, Philippines, October 9, 2015 "Pharmaceutical Packaging and Package Integrity", "Stability of Pharmaceuticals and Drug Degradation Kinetics Overview"

4. Lee Kirsch, "Physiologically-based Pharmacokinetic Models and Tools for Drug Development and Therapeutics", February 21, 2014, Universiti Kebangsaan Malaysia, Kuala Lumpur, Malaysia.
5. Lee Kirsch, "Linking Stability to Manufacturing in the Quality-By-Design Pharmaceutical Development Paradigm", February 20, 2014, The University of Nottingham-Malaysia, Malaysia.
6. Lee E. Kirsch, "Trends in Pharmaceutical Sciences: Education and Research", February 28, 2014, University of Philippines-Manila, Philippines.
7. Lee E. Kirsch, "Drug Degradant Risk Assessment using PBPK Modeling", March 4, 2014, Mahidol University, Thailand.
8. Lee E. Kirsch, "Get Ready→Get Set→Publish: the why, what and how of science writing", March 11, 2014, Mahidol University, Thailand.
9. Lee E. Kirsch, "Modernized Pharmaceutical Stability Evaluation and Packaging Science". March 26, 2014, University of Surabaya, Indonesia.
10. Lee E. Kirsch, "On the Role of Physical Stability in the Chemical Instability of Pharmaceuticals". March 28, 2014, Institut Teknologi Bandung, Indonesia.
11. Lee E. Kirsch, "Kinetics and Mechanisms of Gabapentin Instability", March 29, 2014, Universitas Gadjah Mada, Yogyakarta, Indonesia.
12. Lee E. Kirsch, "Trends in Pharmaceutical Technology Education", April 8, 2014, University of Health Sciences, Vientiane, Lao PDR.
13. Lee E. Kirsch, "Trends in Pharmaceutical Sciences, Manufacturing and Regulatory", Hanoi University of Pharmacy, April 5, 2014, Vietnam.
14. Lee E. Kirsch, "Physiologically-based Pharmacokinetic Models and Tools for Drug Development and Therapeutics Applications". SINATER 2013, Federal University of Pernambuco, Recife, Brazil, 2013.
15. Mo'tasem M. Alsmadi, Stephen D. Stamatis, Lawrence Fleckenstein, and Lee E. Kirsch, "Whole Body Physiologically Based Pharmacokinetic (WBPBPK) Model of Ivermectin (IVM)" 2013, *AAPS Annual Meeting and Exposition*. San Antonio, TX.
16. Nguyen HQ, Stamatis SD, Kirsch LE., "Risk assessment of drug degradants using a physiologically-based pharmacokinetic model approach". 2013, *AAPS Annual Meeting and Exposition*. San Antonio, TX.
17. Radaduen Tinmanee, Stephen D. Stamatis, Lee E. Kirsch, "Modeling Chemical and Physical Instability Pathways of Gabapentin/Excipient Mixtures", 2013, *AAPS Annual Meeting and Exposition*. San Antonio, TX.
18. Nguyen HQ, Stamatis SD, Kirsch LE "Physiologically based risk assessment for drug product degradants with a case study for aniline in rat".. 2012. *Health Sciences Research Week*. University of Iowa. Carver College of Medicine.
19. Radaduen Tinmanee, Stephen D. Stamatis, Lee E. Kirsch, Sarah C. Larsen, Kenneth R. Morris. "The Effect of Excipients on API Stability: Covalent and Polymorphic Transitions." Poster session presented at: 2012 AAPS Annual Meeting and Exposition; 2012 October 14-18; Chicago, IL.
20. Stamatis SD, McLennan MJ, and Kirsch LE, "Architecture of pHUBpk: A portal to active learning environments for understanding rational linkages between drug and patient characteristics and pharmacokinetics", AAPS, Chicago IL, 2012
21. Stamatis SD, McLennan MJ, and Kirsch LE, "Active learning environments for understanding drug distribution, elimination and bioequivalence in pHUBpk on the pharmaHUB", AAPS, Chicago IL, 2012
22. Nguyen H, Stamatis SD, and Kirsch LE, "Risk Assessment of drug degradants using a

- physiologically-based Pharmacokinetic Model Approach", AAPS Chicago IL, 2012
23. Stamatis SD, McLennan MJ, and Kirsch LE, "Kpred and Vdss: Free Tools on the PharmaHUB for Exploring Drug Tissue Partitioning and Distribution", Podium presentation, AIChE National Meeting, Pittsburgh, PA, 2012
 24. Tinmanee, R., Stamatis, S., Huang, H., Ngeachareernkul, P., Kirsch, L. E., AAPS Annual Meeting, "Development of a shelf life prediction model using Bayesian parameter estimation for kinetics of solid state gabapentin degradation", Washington DC, USA, Contributed. (2011).
 25. Tinmanee, R., Stamatis, S., Dempah, E., Munson, E., Kirsch, L. E., AAPS Annual Meeting, "Modeling polymorphic transformations of gabapentin and assessing the effect of excipients using PXRD and ssNMR", Washington DC, USA, Contributed. (2011).
 26. Chanvorachote, B., Qiu, J., Muangsiri, W., Nimmannit, U., Kirsch, L. E., AAPS Annual Meeting and Exposition, "The mechanism between PAMAM dendrimers and lipopeptide (daptomycin)", Washington DC, Contributed. (October 2011).
 27. Tinmanee, R., Stamatis, S., Nguyen, Q., Zong, Z., Kirsch, L. E., NIPTE/FDA Research Symposium, "Formulation of a gabapentin drug degradation model that combines manufacturing and storage stress variables", Rockville, USA, Contributed. (June 2011).
 28. Tinmanee, R., Zong, Z., Kirsch, L. E., NIPTE/FDA Research Symposium, "Role of excipients in the solid state lactamization of gabapentin", Rockville, USA, Contributed. (June 2011).
 29. Qiu, J., Kirsch, L. E., AAPS National Biotechnology Conference, "The effects of aggregation and conformation on the ionization of lipopeptide (Daptomycin)", San Francisco, CA, Contributed. (May 2011).
 30. Buckner, I., Dalal, N., Tinmanee, R., Zong, Z., Huang, H., Qiu, J., Kirsch, L. E., AAPS, "Excipient effects on the solid-state stability of gabapentin", New Orleans, Louisiana, USA, Contributed. (November 2010).
 31. Qiu, J., Yu, L., Kirsch, L. E., AAPS Annual Meeting and Exposition, "Determination of the complex ionization behaviour of daptomycin", New Orleans, Louisiana, Contributed. (November 2010).
 32. Zong, Z., Kirsch, L. E., Kaushal, A., Suryanarayanan, R., Dempah, E., Munson, E., FIP Pharmaceutical Sciences World Congress in Association with the AAPS Annual Meeting and Exposition, "A Kinetic Model for the Solid State Degradation of Gabapentin", New Orleans, Louisiana, Contributed. (November 2010).
 33. Kaushal, A., Dempah, E., Huang, H. G., Qiu, J., Munson, E., Kirsch, L. E., Suryanarayanan, R., FIP Pharmaceutical Sciences World Congress in Association with the AAPS Annual Meeting and Exposition, "Phase transformations in gabapentin during wet granulation and drying", New Orleans, Louisiana, Contributed. (November 2010).
 34. Dempah, K., Kaushal, A., Huang, H. G., Suryanarayanan, R., Kirsch, L. E., Munson, E., FIP Pharmaceutical Sciences World Congress in Association with the AAPS Annual Meeting and Exposition, "Predicting Gabapentin Stability upon Processing using SSNMR", New Orleans, Louisiana, Contributed. (November 2010).
 35. Kirsch, L. E., Department of Chemical and Biological Engineering, Illinois Institute of Technology, "On the Role of Physical Stability on the Chemical Instability of Pharmaceuticals", Chicago, IL, Invited. (October 21, 2010).
 36. Kirsch, L. E., Primera Reunion Internacional De Ciencias Farmaceuticas (RICiFa 2010), "A Case Study on Linking Solid-state Stability to Manufacturing Design in the FDA's Quality-by-Design Pharmaceutical Development Paradigm", Cordoba, Argentina, Invited. (June 25, 2010).
 37. Kaushal, A., Suryanarayanan, R., Zong, Z., Desai, S., Huang, H.-S., Khan, M., Kirsch, L. E.,

- Barich, D. H., Munson, E. J., AAPS Annual Meeting, "Anhydrous and monohydrate gabapentin inter-conversion: Potential implications during solid dosage form manufacture", Los Angeles, Contributed. (2009).
38. Barich, D. H., Munson, E. J., Kaushal, A., Suryanarayanan, R., Zong, Z., Desai, S., Huang, H.-S., Khan, M., Kirsch, L. E., AAPS Annual Meeting, "Characterization of Gabapentin Forms and Stability using Solid-State NMR Spectroscopy", Los Angeles, Contributed. (2009).
39. Zong, Z., Desai, S., Kaushal, A., Barich, D., Huang, H., Munson, E., Suryanarayanan, R., Khan, M., Kirsch, L. E., AAPS Annual Meeting, "The Stabilizing Effect of Moisture on the Solid-State Degradation of Gabapentin", Los Angeles, Contributed. (2009).
40. Zong, Z., Desai, S., Huang, H.-S., Kirsch, L. E., Kaushal, A., Suryanarayanan, R., Barich, D. H., Munson, E. J., Wildfong, P., Buckner, I., Drennen, J., Pingali, K. C., Muzzio, F. J., Kayrak-Talay, D., Litster, J. D., Reklaitis, G., Bogner, R., Khan, M., AIChE Annual Meeting, "The Development of Methods to Link Design Space Models to Product Stability", Nashville, Contributed. (2009).
41. Kirsch, L. E., Symposium presentation at the University of Wisconsin, "Pharmaceutical Chemistry of a Lipopeptide Antibiotic (Daptomycin)", Invited. (March 27, 2009).
42. Qiu, J., Kirsch, L. E., AAPS Annual meeting, "The effects of aggregation on the pharmaceutical chemistry of daptomycin", Atlanta, Contributed. (November 2008).
43. Kirsch, L. E., NIPTE Stakeholders Meeting, "An Introduction to the NIPTE Curriculum", Chicago, Contributed. (April 2008).
44. Kirsch, L. E., Annual AAPS meeting, "Transforming Pharmaceutical Technology Education", San Diego, Invited. (2007).
45. Qiu, J., Kirsch, L. E., AAPS Annual Meeting, "Evaluation of Lipopeptide Aggregation Using Light Scattering, Fluorescence and NMR Spectroscopy", San Diego, Contributed. (November 2007).
46. Desai, S., Kirsch, L. E., AAPS Annual Meeting, "Ortho Substitution Effects in the Hydrolysis of Formanilides", San Diego, Contributed. (November 2007).
47. Naik, H., Kirsch, L. E., Fleckenstein, L., AAPS Annual Meeting, "Population pharmacokinetics of artesunate and its metabolite, dihydroartemisinin", San Diego, Contributed. (November 2007).
48. Chanvorachote, B., Kirsch, L. E., AAPS Annual Meeting, "Studies on the Binding between Daptomycin and PAMAM Dendrimers", San Diego, Contributed. (November 2007).
49. Zong, Z., Kirsch, L. E., AAPS Annual Meeting, "Studies on the Instability of Chlorhexidine", San Diego, Contributed. (November 2007).
50. Kirsch, L. E., AAPS Annual Meeting, "Transforming Pharmaceutical Technology Education: A NIPTE Proposal", Contributed. (November 2007).
51. Kirsch, L. E., Annual PDA Meeting, "NIPTE Roadmap", Las Vegas. (March 2007).
52. Kirsch, L. E., Science and Education Advisory Committee meeting, "NIPTE Roadmap", Chicago, Contributed. (March 2007).
53. Kirsch, L. E., Chemical and Biochemical Engineering Symposium Series, "Physical and Pharmaceutical Chemistry of Daptomycin", The University of Iowa, Invited. (February 15, 2007).
54. Zong, Z., Kirsch, L. E., AAPS meeting, "Kinetic Studies of the Formation of p-Chloroaniline from the Degradation of Chlorhexidine", Nashville, Contributed. (November 2005).
55. Gokhale, M., Kirsch, L. E., AAPS meeting, "Kinetics and Mechanisms of the Glycosylation of Weakly Basic Aromatic Amines and Monosaccharides", Nashville, Contributed. (November 2005).

56. Desai, S., Kirsch, L. E., AAPS meeting, "Preliminary Studies of Ortho Substitution Effects on Amide Hydrolysis using Formanilides as Model Compounds", Nashville, Contributed. (November 2005).
57. Kirsch, L. E., Pharmaceutical Forum, "Depot Injection Systems: Current Uses and Issues", London, England, Invited. (November 2005).
58. Kirsch, L. E., North Carolina Discussion Group, Research Triangle Park, "Adventures in Peptide Degradation Kinetics", Durham, NC, Invited. (June 6, 2005).
59. Gokhale, M., Kirsch, L. E., AAPS Annual Meeting, "The Effects of pH and Buffers on the Kinetics of Kynurenine Glycosylation", Baltimore, MD, Contributed. (November 2004).
60. Kirsch, L. E., Pharmaceutical Microbiology Forum, "Package Integrity Quality Assurance", Fairport, NY, Invited. (October 2004).
61. Gokhale, M., Kirsch, L. E., AAPS Annual Meeting, "Preliminary Kinetic Studies on the Reaction of Kynurenine with D-glucose", Stalt Lake City, Contributed. (October 2003).
62. Kirsch, L. E., University of North Carolina, College of Pharmacy, "Chemical Degradation of Pharmaceutical Peptide", Invited. (April 15, 2003).
63. Kirsch, L. E., Genentech, "The Science Behind Pharmaceutical Packaging Quality Assurance", South San Francisco, CA, Invited. (February 2003).
64. Muangsiri, W., Kirsch, L. E., Annual Meeting of the American Association of Pharmaceutical Scientists, "In Vitro Characterization of Macromolecular Antibiotic Prodrugs", Toronto, Canada, Contributed. (November 2002).
65. Muangsiri, W., Kirsch, L. E., Annual Meeting of the American Association of Pharmaceutical Scientists, "Preparation of Macromolecular Antibiotic Prodrugs", Toronto, Canada, Contributed. (November 2002).
66. Kirsch, L. E., Annual Meeting of the American Association of Pharmaceutical Scientists, "Techniques for Establishing Critical Leakage Specifications", Toronto, Canada, Contributed. (November 13, 2002).
67. Kalvakota, B., Kirsch, L. E., Redmon, M., Thakur, A., Annual Meeting of the American Association of Pharmaceutical Scientists, "The Degradation of (R,R)-formoterol-L-tartrate in Aqueous Solutions", Denver, Colorado, Contributed. (October 2001).
68. Joshi, A., Kirsch, L. E., Annual Meeting of the American Association of Pharmaceutical Scientists, "The Relative Rates of Asparaginy and Glutaminy Deamidation in Glucagon Fragment 22-29 under Acidic Conditions", Denver, Colorado, Contributed. (October 2001).
69. Kirsch, L. E., Pulmonary Delivery and Disposition of Inhaled Aerosols Workshop, Controlled Release Society 28th International Symposium, "Protein and Peptide Stability in the Liquid and Solid States", San Diego, California, Contributed. (June 24, 2001).
70. Joshi, A., Kirsch, L. E., Annual Meeting of the Pharmaceutical Congress of the Americas, "Determination of Relative Cleavage and Deamidation Rates in Acidic Glucagon Solutions to Evaluate Sequence Effects", Orlando, Florida, Contributed. (March 2001).
71. Kirsch, L. E., Pharmacia, "Package Integrity Testing for Sterility Assurance", Portage, MI, Invited. (October 2000).
72. Kirsch, L. E., Cubist Pharmaceutical, "The Role of Aggregation in the Kinetics of Daptomycin Degradation", Cambridge, MA, Invited. (August 2000).
73. Joshi, A. B., Kirsch, L. E., 1999 Annual American Association of Pharmaceutical Scientists Meeting, "Acidic Degradation Pathways of Glucagon", New Orleans, Contributed. (November 1999).
74. Muangsiri, W., Kirsch, L. E., 1999 Annual American Association of Pharmaceutical Scientists Meeting, "Aqueous Degradation of Daptomycin in Alkaline Solutions", New

- Orleans, Contributed. (November 1999).
75. Nguyen, L., Kirsch, L. E., Wiencek, J., 1999 Annual American Association of Pharmaceutical Scientists Meeting, "Effects of Shear Stress on the Structural and Mechanical Characteristics of Glucagon Gel Systems", New Orleans, Contributed. (November 1999).
 76. Zhang, X., Kirsch, L. E., 1999 Annual American Association of Pharmaceutical Scientists Meeting, "Microviscosity of the Emulsion Determined by Fluorescence Polarization", New Orleans, Contributed. (November 1999).
 77. Kirsch, L. E., Zhang, Z., Muangsiri, W., Luner, P., Wurster, D., Redmon, M., 1999 Annual American Association of Pharmaceutical Scientists Meeting, "RR-Formterol (L) Tartrate Development", New Orleans, Contributed. (November 1999).
 78. Kirsch, L. E., Majuru, S., Oh, E., Joshi, A., Luner, P., Wurster, D., Redmon, M., 1999 Annual American Association of Pharmaceutical Scientists Meeting, "S-Oxybutynin Preformulation Studies", New Orleans, Contributed. (November 1999).
 79. Zhang, X., Kirsch, L. E., 1999 Annual American Association of Pharmaceutical Scientists Meeting, "Study of the Mechanism of Thermally-stressed Parenteral Fat Emulsion", New Orleans, Contributed. (November 1999).
 80. Kirsch, L. E., PDA and American Association of Pharmaceutical Scientists Chicagoland discussion groups, "Debunking Pharmaceutical Package Integrity Testing", Chicago, Invited. (September 1999).
 81. Zhang, X., Kirsch, L. E., 1997 Annual American Association of Pharmaceutical Scientists Meeting, "Drug Effects on the Coalescence Rate of Thermally-stressed Emulsions", San Francisco, Contributed. (November 1998).
 82. Nguyen, L. T., Kirsch, L. E., 1998 Annual American Association of Pharmaceutical Scientists Meeting, "Establishing the Microbial Barrier Properties of Pharmaceutical Packaging by Physical Leak Rate Measurements", San Francisco, Contributed. (November 1998).
 83. Kirsch, L. E., Israel Chapter of the PDA, "Pharmaceutical Package Integrity", Herzelia, Israel, Invited. (October 28, 1998).
 84. Kirsch, L. E., Medical College of Virginia, "Pharmaceutical Instability of Peptides", Invited. (September 1998).
 85. Kirsch, L. E., Morton Guazzo, D., PDA Training and Research Center, "Leakage and Parenteral Packaging Seal Integrity", Baltimore, MD, Invited. (July 1998).
 86. Kirsch, L. E., the International Blow-Fill-Seal Operators Meeting, "Current and Future State of Pharmaceutical Package Integrity", Cambridge, MA, Invited. (April 30, 1998).
 87. Kirsch, L. E., Nguyen, L. T., Morton Guazzo, D., Scheire, R., Muangsiri, W., Western PDA meeting, "Methods for the Development of Indirect Correlations between Physical Leak Rate Methods and Microbial Ingress into Parenteral Packaging", San Francisco, Contributed. (March 1998).
 88. Kirsch, L. E., ESI-Lederle, "Current Issues in Pharmaceutical Container/Closure Integrity Technologies", Invited. (February 2, 1998).
 89. Nguyen, L. T., Gerth, R., Kirsch, L. E., 1997 Annual American Association of Pharmaceutical Scientists Meeting, "A Model for Predicting Helium Leak Rates of Defective Sealed Vials and Its Application in the Validation of Helium Leak Rate Method for Pharmaceutical Container/Closure Systems", Boston, Contributed. (November 1997).
 90. Zhang, X., Kirsch, L. E., 1997 Annual American Association of Pharmaceutical Scientists Meeting, "An Assessment of Techniques for Evaluating the Physical Stability of Parenteral Microemulsions", Boston, Contributed. (November 1997).

91. Nguyen, L. T., Gerth, R., Moeckly, C. S., Kirsch, L. E., 1997 Annual American Association of Pharmaceutical Scientists Meeting, "Correlation of Mass Spectrometry-based Helium Leak Measurements to Microbial Ingress for Pharmaceutical Container/Closure Integrity Testing", Boston, Contributed. (November 1997).
92. Kirsch, L. E., Executive MBA program offered by the College of Business Administration at The University of Iowa, "A Technologist's View of the Pharmaceutical Industry", Invited. (August 1997).
93. Kirsch, L. E., Glaxo Welcome, "Pharmaceutical Container/Closure Integrity Technologies", Invited. (April 14, 1997).
94. Kirsch, L. E., PDA International Congress, "PDA Container/Closure Study", Osaka, Japan, Invited. (February 18, 1997).
95. Nguyen, L., Moeckly, C., Kirsch, L. E., 1996 Annual American Association of Pharmaceutical Scientists Meeting, "Pharmaceutical Container Closure Integrity by Mass Spectrometry-based Leak Detection", Seattle, Contributed. (1996).
96. Kirsch, L. E., 50th Annual PDA meeting, "Application of Mass Spectrometry Leak Testing to Pharmaceutical Package Integrity Quality Assurance", Philadelphia, Invited. (November 20, 1996).
97. Kirsch, L. E., Seminar at Fujisawa USA, "Pharmaceutical Container/Closure Integrity Technologies", Chicago, Invited. (April 19, 1996).
98. Sihn, Y., Guillory, K., Kirsch, L. E., 1995 Annual American Association of Pharmaceutical Scientists meeting, "Degradation Kinetics and Interaction Studies of Taurolidine Equilibrium Products with PVP in Aqueous Media", Contributed. (1995).
99. Kirsch, L. E., 1995 Annual American Association of Pharmaceutical Scientists Meeting, "Challenges in the Sterilization of Injectable Disperse Systems", Miami, Invited. (November 1995).
100. Kirsch, L. E., Genetics Institute, "Re-engineering Pharmaceutical Product Development", Andover, Invited. (December 1994).
101. Kirsch, L. E., Redmon, M. P., 16th Annual Midwest Biopharmaceutical Statistics Workshop, "Quality Tools Applied to Pharmaceutical Product Development: Quality Function Deployment, Business Function Deployment, and Failure Modes and Effects Analysis", Invited. (May 1993).
102. Kirsch, L. E., Redmon, M. P., Arden House Conference, "Biopharmaceutical Product Development", Invited. (February 1993).
103. Kirsch, L. E., Annual American Association of Pharmaceutical Scientists Meeting, "New Method for Predicting Arrhenius Behavior in Accelerated Drug Degradation Studies", Washington DC, Contributed. (October 1991).
104. Kirsch, L. E., Virginia Commonwealth University, School of Pharmacy faculty and graduate students, "Degradation Kinetics Short Course and Simulation Laboratory", Invited. (April 1991).
105. Stout, P., Khoury, N., Mauger, J., Kirsch, L. E., Annual American Association of Pharmaceutical Scientists Meeting, "Human Zinc Insulin Suspension Release Kinetics", Las Vegas, Nevada, Contributed. (November 1990).
106. Kirsch, L. E., Land O Lakes meeting, "Protein Reactivity", Invited. (June 1990).
107. Kirsch, L. E., Lefeber, D., Riggin, R., Gearhart, D., Clone to Clinic Biotechnology Meeting, "The Susceptibility of Human Growth Hormone to In-process Degradation", Amsterdam, the Netherlands, Contributed. (March 1990).
108. Kirsch, L. E., University of Nebraska, College of Pharmacy, Pharmaceutical Sciences Research Retreat, "Strategies for Research Collaboration with Industrial Sites",

- Boystown, Nebraska, Invited. (November 1989).
109. Mauger, K., Shaeiwitz, J., Mauger, J., Kirsch, L. E., Annual American Association of Pharmaceutical Scientists meeting, "Mechanism of Crystalline Zinc Insulin Dissolution", Atlanta, Georgia, Contributed. (October 1989).
110. Kirsch, L. E., Annual American Association of Pharmaceutical Scientists meeting, "Protein Degradation Pathways in Parenteral Dosage Forms", Atlanta, Georgia, Invited. (October 1989).
111. Gearhart, D., Lefeber, D., Riggin, R., Kirsch, L. E., Annual American Association of Pharmaceutical Scientists meeting, "The Effects of Parenteral Sterilants on the Generation of Protein Degradation Products During Pharmaceutical Processing", Atlanta, Georgia, Contributed. (October 1989).
112. Khoury, N., Stout, P., Mauger, J., Shaeiwitz, J., Kirsch, L. E., ACS Colloid and Surface Science Symposium, "Dissolution of Recombinant Human Insulin Crystal", Seattle, Washington, Contributed. (June 1989).
113. Kirsch, L. E., Rho Chi lecturer, "Biotechnic Drug Development", Duquesne University, Invited. (December 1988).
114. Stout, P., Mauger, J., Koury, N., Kirsch, L. E., American Association of Pharmaceutical Scientists meeting, "Dissolution Characteristics of Changing Mixtures of Amorphous: Crystalline Humulin Zinc Insulin", Orlando, Florida, Contributed. (November 1988).
115. Gearhart, D., Kirsch, L. E., Annual American Association of Pharmaceutical Scientists meeting, "Dry-state Deamidation of Glucagon", Orlando, Florida, Contributed. (November 1988).
116. Kirsch, L. E., Short course presented to the West Virginia University, School of Pharmacy graduate students, "Degradation Kinetics Short Course and Simulation Laboratory", Invited. (May 1988).
117. Kirsch, L. E., West Virginia University, University of Kentucky, Duquesne University, Medical College of Virginia, Biochemical Development Seminar Series, "The Role of Transpeptidation and Deamidation in the Pharmaceutical Instability of Proteins and Peptides", Invited. (1987).
118. Kirsch, L. E., Biotechnology symposium at the American Association of Pharmaceutical Scientists meeting, "The Role of Transpeptidation and Deamidation in the Pharmaceutical Instability of Proteins and Peptides", Boston, Invited. (June 1987).
119. Kirsch, L. E., Short Course presented to the West Virginia University, School of Pharmacy graduate students, "Degradation Kinetics Short Course and Simulation Laboratory", Invited. (May 1987).
120. Kirsch, L. E., Bucko, J., Smith, W., Akers, M., Hargrove, W., 1986 American Association of Pharmaceutical Scientists meeting, "Development of a Quantitative Model for the In Vitro and In Vivo Delivery Kinetics of CRIS, a Novel Intravenous System", Washington DC, Contributed. (November 1986).
121. Stout, P., Mauger, J., Kirsch, L. E., Khoury, N., Sheliga, T., Annual American Association of Pharmaceutical Scientists, "Dissolution of Lente Insulins", Washington DC, Contributed. (November 1986).
122. Kirsch, L. E., Humana Corporate Center, "IVAC CRIS System Performance", Louisville, Kentucky, Invited. (May 1986).
123. Kirsch, L. E., Delaware Valley Society of Hospital Pharmacists, "Drug Delivery with the IVAC CRIS System", Philadelphia, Pennsylvania, Invited. (April 1986).
124. Kirsch, L. E., Graduate Faculty Seminar, "Kinetics and Pharmacokinetics of Intravenous Drug Delivery", School of Pharmacy West Virginia, Invited. (January 1986).

125. Kirsch, L. E., American Society of Hospital Pharmacists 20th Midyear Clinical Meeting, "Drug Delivery with the IVAC CRIS System", New Orleans, Louisiana, Contributed. (December 1985).
126. Kirsch, L. E., Smith, W., Massey, E., Bechtel, L., Davies, D., Thirty-seventh National Meeting of the Academy of Pharmaceutical Sciences, "The Evaluation of Human Insulin Formulations by Kinetic Analysis of Time-Action Profiles in Rabbits", Philadelphia, Pennsylvania, Contributed. (October 1984).
127. Kirsch, L. E., Notari, R., 130th American Pharmaceutical Association Annual Meeting, "Kinetics and Mechanism of In Vitro Prodrug Conversion to Cytarabine (ARA-C)", New Orleans, Louisiana, Contributed. (April 1983).
128. Kirsch, L. E., Notari, R., 130th American Pharmaceutical Association Annual Meeting, "Pharmacokinetics of Prodrug Bioconversion to Cytarabine (ARC-C)", New Orleans, Louisiana, Contributed. (April 1983).

Grantsmanship

Over 55 research grants and contracts

PROFESSIONAL, GOVERNMENTAL, UNIVERSITY AND OTHER SERVICE

Professional/Clinical Services and Committees

Internal Committee

University of Iowa STEM Advisory Council. (2011 - 2013).
College of Pharmacy Curriculum Re-engineering Task Force, "Transformers". (2009 - 2014).
Faculty Senate. (2008 - 2011).
College of Pharmacy IT Committee Chairman. (2008 - 2009).
Graduate College Council. (2006 - 2009).
College of Pharmacy Admissions Committee. (2007 - 2008).
College of Pharmacy Curriculum Committee. (2006 - 2007).
College of Pharmacy Continuing Education Oversight Committee. (2003 - 2006).
College of Pharmacy Industrial Consortium. (2003 - 2006).
College of Pharmacy Admissions Committee Chairman. (2001 - 2003).
College of Pharmacy Research Equipment Committee. (1999 - 2003).
Pharmaceutics Search Committee Chairman. (2001 - 2002).
Ad Hoc Planning Committee for the 1999 Collegiate Research Retreat. (1999).
Advisory Committee to the Vice President for Research for Medical and Biological Sciences. (1998 - 1999).

General

Member of the American Association of Pharmaceutical Scientists (1993 – present)
Member of USP <1207> Expert Panel. (January 2011 - 2013).
Editor-in-chief, AAPS Pharmaceutical Science and Technology Journal. (July 2008 – December, 2014).
Faculty Committee Leadership in the National Institute for Pharmaceutical Technology and Education, Faculty Committee, Chairman and Leadership Team (2009-2011): Education

Roadmap, Co Chairman: Pharmaceutical Material Section of Technology Roadmap. (2005 - 2008). Chaired the education committee for NIPTE working on the design of a national curriculum in pharmaceutical technology. (2005 – 2008)

Editorial Advisory Board, Drug Development and Industrial Pharmacy. (June 2000 - 2009).
Member of the Parenteral Drug Association Executive Committee. (2000 - 2002).
Member of USP <1059> Advisory Committee of Excipient Quality. (January 2009 - January 2011).

PQRI Working Group Member, Aseptic Processing. (2003 - 2008).
Regulatory Affairs Advisory Board for the Parenteral Drug Association. (2003 - 2008).
Scientific Advisory Board for the Parenteral Drug Association. (2003 - 2008).
Strategic Planning Committee for the Parenteral Drug Association. (2003 - 2008).
Editorial Advisory Board, Pharmaceutical Development and Technology. (1995 - 2008).
Editor, The PDA Journal of Pharmaceutical Science and Technology. (February 2000 - June 2008).


Reviewer for United Arab Emirate University Research Fund. (2004).
The University of Iowa Research Review Committee in the Biological Sciences. (2003 - 2004).
Reviewer for State of Indiana 21st Century Fund proposals. (2003).
Member of the Ad Hoc National Institutes of Health SBIR and STTR Study Section for Drug Development and Delivery. (2000).

Reviewer for the National Science Foundation Directorate for Engineering. (2000).
Member of the Pharmaceutical Sciences Alliance Council, Aseptic Processing Advisory Panel, PDA-TRI Container/Closure Applied Research Task Force, and Faculty member for the Parenteral Drug Association Research and Training Center. (1998 - 1999).
Chairman of the American Association of Pharmaceutical Scientists Sterile Products Focus Group. (1997).

AAPS Pharmaceutical Technology Section Leadership Team. (1995 - 1997).
Conference co-chairman (with Dr. John Clements of the Royal Pharmaceutical Society of Great Britain) for the 1996 Arden House Conferences. (1996).

ATTACHMENT B

CONFIDENTIAL - PURSUANT TO PROTECTIVE ORDER

Zlatan Coralic, PharmD, BCPS
Zlatan.Coralic@ucsf.edu**EDUCATION**

Jul 2008 - Jul 2009	Pharmacy Practice Residency, PGY-1 ASHP Accredited University of California, San Francisco (UCSF) Residency Director: Cathi Dennehy, PharmD San Francisco, California
Aug 2005 - Jun 2008	Doctor of Pharmacy University of Southern Nevada (USN) College of Pharmacy Henderson, Nevada
Sep 2000 - Jun 2005	B.S. in Biology (Cell and Molecular concentration) Minor in Chemistry University of Nevada, Las Vegas (UNLV) Las Vegas, Nevada

LICENSES / CERTIFICATIONS

Nov 2012	Board Certified Pharmacotherapy Specialist Board of Pharmacy Specialties
Oct 2009	Pediatric Advanced Life Support (PALS)
Jul 2009	Advanced Teaching Certificate UCSF School of Pharmacy
Jul 2008 - present	Registered Pharmacist #17361 Nevada State Board of Pharmacy
Jul 2008 - present	Registered Pharmacist #61422 California State Board of Pharmacy
Jun 2009	Certified Clinical Preceptor
Jul 2006 - present	Advanced Cardiac Life Support (ACLS)
Sep 2005- present	Basic Life Support (BLS)

PROFESSIONAL EXPERIENCE

Oct 2013 – present	Assistant Clinical Professor of Emergency Medicine (WOS) UCSF School of Medicine (Department of Emergency Medicine) Director: Peter Sokolove, MD
Jul 2009 – Nov 2016 Nov 2016 – present	Health Sciences Assistant Clinical Professor (Pharmacy/WOS) Promotion: Health Sciences Associate Clinical Professor (Pharmacy/WOS) UCSF School of Pharmacy Director: B. Joseph Guglielmo, PharmD
Jul 2009 – present	Emergency Medicine Clinical Pharmacist UCSF Medical Center Director: Daniel Wandres, PharmD
Jul 2010 – present	Clinical Preceptor – Emergency Medicine Pharmacy (PGY 1-2) and Medical (PGY 3-4) Residents
Oct 2006 - Jul 2008	Pharmacist Intern University Medical Center, Southern Nevada (UMCSN) Director of Pharmaceutical Services: Diana Bond, RPh
May 2005 - Jul 2008	Pharmacist Technician / Intern Walgreens #3873 Las Vegas, Nevada Pharmacy Supervisor: Matt Forster, PharmD

PROFESSIONAL ORGANIZATIONS / AFFILIATIONS / LEADERSHIP

Jul 2016 – Jul 2018	Vice Chair / Chair / Past Chair: ASHP Science Advisory Group on Emergency Care
Jan 2016 – Jul 2017	Lead Institution Clinical Pharmacist: ESETT Multicenter Randomized Trial ClinicalTrials.gov: NCT01960075
Oct 2015 - present	Reviewer: Annals of Emergency Medicine
Oct 2014	Lead Author: Proposition 44 (national). American College of Emergency Physician Policy Statement: Support for Clinical Pharmacists as Part of the Emergency Medicine Team
Oct 2014 – present	Reviewer: Emergency Medicine Journal (British Medical Journal)
Aug 2013 – Aug 2018	ASHP's Science Advisory Group on Emergency Care Member
Dec 2012- present	Reviewer: American Journal of Health-System Pharmacy
Jun 2011- present	Contributor: Academic Life in Emergency Medicine Blog
Feb 2010 – present	Founding Member: California Emergency Medicine Pharmacy Network
Sep 2008	UCSF Pharmacy Residency Chief Resident
Oct 2008 – Oct 2009	California Society of Health Systems Pharmacists (CSHP)
Oct 2007- present	American Society of Health Systems Pharmacists (ASHP)
Sep 2005- Jun 2006	Class President USN College of Pharmacy

RESEARCH AND SCIENTIFIC WRITING

Coralic, Z (Associate Editor). Emergency Management of Infectious Diseases, 2nd edition. [Textbook]. Cambridge University Press. Publication date: September 8, 2018.

Avdagic K, Geier M, **Coralic Z**, Finley P. Evaluation of the Impact of a Multimodel Intervention on Prescribing Patterns of Sedative-Hypnotics in a Behavioral Health System. *Prim Care Companion CNS Disord* 2018;20.

Morgan SR, Acquisto NM, **Coralic Z**, et al. Clinical pharmacy services in the emergency department. *Am J Emerg Med*. 2018 Oct;36(10):1727-1732.

Coralic Z, et al. Ketamine Procedural Sedation in the Emergency Department of an Urban Tertiary Hospital in Dar es Salaam, Tanzania. *Emerg Med J*. 2018 Apr;35(4):214-219.

Li, K., Vo, K., Addo N., Lee, B., **Coralic, Z**. Effect of a single dose of i.v. ondansetron on QTc interval in emergency department patients. *Am J Health Syst Pharm*. 2018 Mar 1;75(5):276-282.

Coralic Z, Hayes BD. Emergency Medicine Pharmacists on an International Scale. *Emerg Med J*. *Emerg Med J*. 2017 Aug; 34(8): 492-493.

Coralic Z, Kim SA, Vinson DR. Prochlorperazine-Induced Hemidystonia Mimicking Acute Stroke. *Western Journal of Emergency Medicine*. 2015;16(4):1-3.

Burnett MM, Zimmermann L, **Coralic Z**, et al. A simple text-messaging intervention is associated with improved door-to-needle times for acute ischemic stroke. *Stroke*. 2014 Dec;45(12):3714-6.

Coralic Z, Kanzaria HK, Bero L, Stein J. Staff perceptions of an on-site clinical pharmacist program in an academic emergency department after one year. *West J Emerg Med*. 2014 Mar;15(2):205-10.

Gertler SA, **Coralic Z**, et al. Root cause analysis of ambulatory adverse drug events that present to the emergency department. *J Patient Saf*. 2014 Feb 27.

Wallis, L & Reynolds, T (Eds - **Coralic, Z**). 2013. *AFEM Handbook of Acute and Emergency Care*. (Anticoagulation pp. 959-965). Cape Town: Oxford University Press Southern Africa.

James KT, Detz A, **Coralic Z**, Kanzaria H. Levamisole contaminated cocaine induced cutaneous vasculitis syndrome. *West J Emerg Med*. 2013 Sep;14(5):448-9.

Coralic Z, Lenhoff T, Kanzaria HK, Gerona R. A 120-hour case of priapism from an over-the-counter herbal supplement. *Ann Pharmacother*. 2013 Feb;47(2):289-90.

Kanzaria HK, Farzan N, **Coralic Z**. Adie's tonic pupil. *West J Emerg Med*. 2012 Dec;13(6):543.

Coralic Z, Nemer JA. Acute Pain Management. In: GEMSoft [electronic media]. Lin M, Chin R (eds). GEMSoft (General Emergency Medicine Software). Queensland, Australia: Pemsoft Pty Ltd. In press, 2012.

Coralic Z, Duong D. Acute Agitation Management. In: GEMSoft [electronic media]. Lin M, Chin R (eds). GEMSoft (General Emergency Medicine Software). Queensland, Australia: Pemsoft Pty Ltd. In press, 2012

Coralic Z, Mongelluzzo J. Procedural Sedation. In: GEMSoft [electronic media]. Lin M, Chin R (eds). GEMSoft (General Emergency Medicine Software). Queensland, Australia: Pemsoft Pty Ltd. In press, 2012

Chung-Esaki H, Knight R, Noble J, Wang R, **Coralic Z**. Detection of Acute Pulmonary Embolism by Bedside Ultrasound in a Patient Presenting in PEA Arrest: A Case Report. *Case Reports in Emergency Medicine*, vol. 2012, Article ID 794019, 5 pages, 2012.

Frymoyer A, Hersh AL, **Coralic Z**, Benet LZ, Joseph Guglielmo B. Prediction of vancomycin pharmacodynamics in children with invasive methicillin-resistant staphylococcus aureus infections: A monte carlo simulation. *Clin Ther*. 2010 Mar;32(3):534-42.

Avdagic Z, Purisevic E, Omanovic S, Coralic Z. Artificial intelligence in prediction of secondary protein structure using CB513 database. Summit on Translat Bioinforma. 2009 Mar 1; 2009:1-5.

SELECTED SOCIAL MEDIA SCIENTIFIC CONTRIBUTIONS

Academic Life in Emergency Medicine (ALiEM.com) Contributions

Coralic, Z. *ALiEM*. "Trick of the Trade: Mix Ceftriaxone IM with Lidocaine for Less Pain." Web. 6 Nov. 2014. <http://bit.ly/1CpVbWi>

Coralic, Z. *ALiEM*. "I am giving prochlorperazine. Should I give diphenhydramine too?" Web. 3 Sep. 2014. <http://bit.ly/12d7KUg>

Coralic, Z. *ALiEM*. "My EpiPen expired! Can I still use it?" Web. 19 May 2014. <http://bit.ly/1tyZtk3>

Coralic, Z. *ALiEM*. "New Antibiotic Dalbavancin: Should we use this in the ED?" Web. 12 May 2014. <http://bit.ly/1z2tUUf>

Coralic, Z. *ALiEM*. "The Ultimate Consult Service: Emergency Pharmacists." Web. 3 Oct 2013. <http://bit.ly/1y8fftu>

Coralic, Z. *ALiEM*. "The Dirty Epi Drip: IV Epinephrine When You Need It." Web. 27 Jun 2013. <http://bit.ly/1tyZxjw>

Coralic, Z. *ALiEM*. "On the Horizon: Propofol for Migraines." Web. 25 May 2013. <http://bit.ly/15Io7dK>

Coralic, Z. *ALiEM*. "One-dose vancomycin for SSTIs: Just don't do it." 23 Jan 2013. Web. <http://bit.ly/124pYbs>

Coralic, Z. *ALiEM*. "Trick of the Trade: Converting % to mg/mL." 17 Jun 2012. Web. <http://bit.ly/1vWKffU>

Podcasts

Herbert, M. (Producer), Lin, M., Poree, L., Coralic, Z. (Contributors). 2015 Nov 1. "Lin Sessions – Intrathecal Pumps in Emergency Medicine" Available through subscription <http://www.emrap.org/> [Audio Podcast].

Herbert, M. (Producer), Lin, M., and Coralic, Z. (Contributors). 2014 Jan 1. "Lin Sessions - PO vs IV Clindamycin - Dirty Epi Drip - Propofol for Migraines." Available through subscription <http://www.emrap.org/> [Audio Podcast].

Herbert, M., (Producer), Lin, M., and Coralic, Z. (Contributors). 2015 Jan 1. tPA in Pregnancy? Available through subscription <http://www.emrap.org/> [Audio Podcast].

PRESENTATIONS

Apr 2019	Drug Shortages: Woes and Opportunities Vituity Spring Symposium, San Diego, CA: <i>Lecture</i>
Oct 2018	Updates in Reversal of Anticoagulation Advanced Critical Care & Emergency Nursing, Las Vegas, NV: <i>Lecture</i>
Oct 2018	A Discussion about the Opioid Epidemic Advanced Critical Care & Emergency Nursing, Las Vegas, NV: <i>Lecture</i>
Oct 2018	Drug Shortages: Woes and Opportunities Advanced Critical Care & Emergency Nursing, Las Vegas, NV: <i>Lecture</i>
Apr 2018	Hyponatremic Emergencies in the ED High Risk Emergency Medicine, Maui, Hawaii: <i>Lecture</i>

CONFIDENTIAL - PURSUANT TO PROTECTIVE ORDER

Dec 2017 **Opioids for Pain: Drug Seeking Behavior, Acute Pain Management, and Drug Monitoring Databases**
ASHP 2017 Mid-Year Meeting, Orlando, FL: *Lecture*

Nov 2017 **EM Meds: Pearls and Pitfalls**
Advanced Critical Care & Emergency Nursing, Las Vegas, NV: *Lecture*

Dec 2016 **Stop the Bloodshed: What Every Pharmacists Needs to Know About Anticoagulation Reversal**
ASHP 2016 Mid-Year Meeting, Las Vegas, NV: *Lecture*

May 2016 **Medication Price Gouging in Emergency Medicine**
Essentials of Emergency Medicine, Las Vegas, NV: *Lecture*

May 2016 **Dangerous Drug Interactions in Emergency Medicine**
Essentials of Emergency Medicine, Las Vegas, NV: *Lecture*

May 2016 **Careful with Some of These in the Resus Room**
Essentials of Emergency Medicine, Las Vegas, NV: *Lecture*

April 2016 **Emergent Anticoagulation Reversal**
CEP America continuing education (Long Beach, CA; Chicago, IL; San Francisco, CA): *Lecture*

Mar 2016 **NOACS in the ED**
Kaiser South San Francisco CE: *Lecture*

Dec 2015 **ASHP Clinical Pearls Session**
ASHP 2014 Mid-Year Meeting, New Orleans, LA: *Lecture*

Dec 2015 **The Use of Ketamine in a Low Resource Hospital: Dar es Salaam, Tanzania**
ASHP 2014 Mid-Year Meeting, New Orleans, LA: *Poster presentation*

Nov 2015 **A Drug Study Sponsored by Industry...What Does That Mean?**
Essentials of Emergency Medicine - Los Angeles, CA: *Lecture/Livestream*

Nov 2015 **Novel Antibiotics: Should We Use These in the ED?**
Essentials of Emergency Medicine - Los Angeles, CA: *Lecture/Livestream*

Nov 2015 **What Happens In July...Stays in July!**
Essentials of Emergency Medicine - Los Angeles, CA: *Lecture/Livestream*

Nov 2015 **Common Medication Errors in the ED**
Essentials of Emergency Medicine - Los Angeles, CA: *Lecture/Livestream*

Oct 2015 **Paralyzed and Awake: Lessons from ED Intubation Research**
UCSF Clinical Pharmacy Research Seminar Series: *Lecture*

Aug 2015 **Treatment of Skin and Soft Tissue Infections in the ED**
UCSF Emergency Medicine Conference: *Lecture*

Aug 2015 **Common Pitfalls with Antibiotics**
UCSF Emergency Medicine Conference: *Lecture*

Jun 2015 **Blood Thinners – Pearls and Pitfalls**
High Risk Emergency Medicine San Francisco Conference: *Lecture*

Jun 2015 **Medication Errors - Pearls and Pitfalls**
High Risk Emergency Medicine San Francisco Conference: *Lecture*

May 2015 **Opioids in the ED**
UCSF School of Medicine Emergency Medicine Elective: *Lecture*

April 2015	Drugs in Pregnancy in Emergency Medicine UCSF Emergency Medicine Conference: <i>Lecture</i>
Dec 2014	Perceived Value of Resource-Specific Treatment Protocols in Dar es Salaam, Tanzania ASHP 2014 Mid-Year Meeting, Anaheim, CA: <i>Poster Presentation</i>
Dec 2014	Demystifying Acute Management of Atrial Fibrillation ASHP 2014 Mid-Year Meeting, Anaheim, CA: <i>Lecture</i>
Dec 2014	The Errors We Make... ASHP 2014 Mid-Year Meeting, Anaheim, CA: <i>Lecture</i>
Oct 2014	Adverse Drug Events in the Community Continuous Pharmacy Education; Alameda Highland Hospital: <i>Lecture</i>
Oct 2014	Fun with Drugs in the ED UCSF Emergency Medicine Conference: <i>Lecture</i>
Jun 2014	Your Medications: Making Sense of Treatments, Benefits, and Risks UCSF Osher Mini Medical School for the Public: <i>Lecture / YouTube Series</i>
May 2014	Emerging in the ED: Primer for Starting in the Emergency Department ASHP: <i>Webinar</i> (460 attendees)
Apr 2014	Toxicology Review UCSF Emergency Department; Department of Nursing: <i>Lecture</i>
Apr 2014	A Qualitative Study Evaluating the Current Landscape of Healthcare Social Media and Podcasts UCSF Spring Research Seminar: <i>Poster Presentation</i>
Dec 2013	Post Rapid-Sequence-Intubation Analgesia and Sedation Practices ASHP 2013 Mid-Year Meeting/Society for Academic Emergency Medicine: <i>Poster Presentation</i>
Dec 2013	Root-Cause Analysis of Adverse Drug Events Leading to an Emergency Department Visit ASHP 2013 Mid-Year Meeting/Society for Academic Emergency Medicine: <i>Poster Presentation</i>
Dec 2013	Cannabinoid Induced Hyperemesis Syndrome & Treatment ASHP 2013 Mid-Year Meeting: Hot Topics in Emergency Medicine: <i>Lecture</i>
Nov 2013	Controversies in Migraine Management / Fun with Drugs in the ED UCSF's Continuing Medical Education Series: Topics in Emergency Medicine: <i>Lecture</i>
Oct 2013	Emergency Department Clinical Pharmacists: Pros and Cons CSHP 2013 Annual Meeting: <i>Lecture</i>
Dec 2012	Give Me Fat, or Give Me Death! The Use of Fat Emulsion Therapy for Calcium Channel Blockers and Other Toxicities ASHP 2012 Mid-Year Meeting: Hot Topics in Emergency Medicine: <i>Lecture</i>
Dec 2012	Impact of ED Pharmacists in Improving Door-to-tPA Administration Times in Ischemic Stroke ASHP 2012 Mid-Year Meeting: <i>Poster Presentation</i>
Dec 2012	Prospective Observational Study of Adverse Drug Events Leading to an Emergency Department Visit Identified by a Clinical Pharmacist ASHP 2012 Mid-Year Meeting: <i>Poster Presentation</i>
Dec 2012	Prothrombin Complex Concentrates INR Dose Response Analysis in Patients with Intracranial Hemorrhage: PIDRA-ICH Study

CONFIDENTIAL - PURSUANT TO PROTECTIVE ORDERASHP 2012 Mid-Year Meeting: *Poster Presentation*

Nov 2012	Simulation Training in Emergency Medicine Association of American Medical Colleges (AAMC) national conference in San Francisco: <i>Simulation</i>
Apr 2012	Emergency Department Override Medication List Pharmacy and Therapeutics Committee at UCSF: <i>Policy Approval</i>
Apr 2012	UCSF Nursing Grand Rounds: Code Stroke UCSF Department of Nursing: <i>Lecture</i>
Jan 2012	Emergency Medicine Pharmacotherapy – Global Initiative Emergency Medicine Conference; Dar es Salaam, Tanzania: <i>Lecture</i>
Jan 2012	Medication Use in Pregnancy – Global Initiative Emergency Medicine Conference; Dar es Salaam, Tanzania: <i>Lecture</i>
Dec 2011	Emergency Medicine Clinical Pearls - tPA and ED Pharmacists ASHP 2011 Mid-Year Meeting: <i>Lecture</i>
Oct 2011	California Poison Control Center Rounds – GHB Ingestion California Poison Control Center San Francisco Division: <i>Lecture</i>
Jun 2011	California Poison Control Center Rounds – Amphetamines from India California Poison Control Center San Francisco Division: <i>Lecture</i>
May 2011	Successful Implementation of Emergency Department Clinical Pharmacists at UCSF UCSF Spring Research Seminar: <i>Poster Presentation</i>
Aug 2010 - present	ED Nursing Annual In-service: Meds in the Code Room UCSF Medical Center Emergency Department: <i>Lecture</i>
May 2009	Current Recommended Dosing for Vancomycin in Children is Inadequate – a Montecarlo Simulation UCSF Spring Research Seminar <i>Poster Presentation</i> , Western States Conference, and UCSF Pharmacy and Therapeutics Committee
Nov 2008	Proposal for Addition to UCSF's Formulary: Regadenoson UCSF Pharmacy and Therapeutics Committee: <i>Policy Approval</i>
Dec 2007	Treatment of Cysticercosis UMCSN: <i>Student Lecture</i>
Nov 2007	Diabetic Medications UMCSN – Family Resource Center Services: <i>Community Outreach Lecture</i>
Oct 2007	Detecting EPS in Patients on Metoclopramide UMCSN: <i>Student Lecture</i>
Jun 2007	Maraviroc in Antiretroviral Experienced HIV Patients UMCSN: <i>Student Lecture</i>
Dec 2006	Etiology and Treatment of Pulmonary Fibrosis USN College of Pharmacy: <i>Student Lecture</i>
Apr 2006	OTC Supplements: Garlic USN College of Pharmacy: <i>Student Lecture</i>

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TEACHING EXPERIENCE

Year(s)	Quarter	Course Number and Title	Nature of Contribution	Hours	Student#
2019	Fall	Stroke	Lecturer	2	120
2015 - 2017	Winter	Critical Thinking	Lecturer	1	120
2015	Spring	CNS Drugs in the ED PC 123	Lecturer	2	120
2012- present	Spring	Management of Acute Coronary Syndrome	Lecturer	2	120
2010 - 2015	Spring	ICU Elective: Toxicology	Lecturer	1	30
2009	Spring	Pediatric Elective Juvenile Idiopathic Arthritis	Lecturer	1	50
2008 - present	Spring	Clinical Pharmacology 120 Acid – Base	Lecturer	2	120
2009	Spring	Physical Assessment Seminar Blood Pressure Measurement	Instructor	1	45
2009	Spring	Biochemistry 112 Hepatic Encephalopathy	Mock Patient Role	1	120
2009	Winter/Spring	Ambulatory Care	Preceptor	480	8
2008 - 2018	Fall	Clinical Pharmacology 111 OTC: Diarrhea, Gas, and Hemorrhoids	Lecturer	2	120
2008	Fall	Clinical Pharmacology 130 Headaches	Lecturer	2	120
2008	Fall	Clinical Pharmacology 130	Conference Leader	48	30

SPECIALIZED TRAINING / OTHER EXPERIENCE

Feb 2018	Hospital Emergency Response Team (HERT) Training FEMA's Center for Disaster Preparedness, Anniston, AL
Jul-Sep 2017	STATA Statistical Analysis Course (BIOSTAT 212) UCSF Department of Epidemiology and Biostatistics
Feb 2015	First Responder for Implantable Drug Infusion Systems Training in interrogation and emergent management of common intrathecal pump malfunctions UCSF Department of Anesthesia and Neuromodulation
Oct 2014	Emergency Department Violence Training: Code 100. Training in approach, restraint, and treatment of agitated patients in the Emergency Department UCSF Department of Emergency Medicine
Jul-Sep 2011	Training in Clinical Research (EPI 202) UCSF Department of Epidemiology and Biostatistics
Jan-Apr 2014	Scientific Writing Course UCSF Department of Surgery

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HONORS AND AWARDS

Jan 2018 & Jan 2019	Top 50 Peer-Reviewer Annals of Emergency Medicine
Dec 2015	Employee of the Year UCSF Department of Emergency Medicine
Aug 2015	Excellence in Teaching Award UCSF Academy of Medical Educators
Jun 2012 & 2014	Clinical Preceptor of the Year Department of Clinical Pharmacy
Aug 2012	ASHP New Investigator Award Research: Prospective Observational Study of Adverse Drug Events Leading to an Emergency Department Visit Identified by a Clinical Pharmacist
Jan 2010	Employee of the Month UCSF Medical Center Department of Emergency Medicine
May 2009	Gary Rifkind Award - Best Research UCSF's Spring Research Seminar
Nov 2007	ASHP Clinical Skills Competition Local Competition Finalist
Aug 2007	USN Annual Scholarship
Sep 2000	Millennium Scholarship of Nevada

EXPERT WITNESS WORK

<u>Year</u>	<u>Law Firm</u>	<u>Type of Work</u>
2019	Dechert LLP (Par vs Eagle)	Review/Opinion/ (ongoing)
2019	Dechert LLP (Par vs Sandoz)	Review/Opinion/ (ongoing)
2019	Floyd, Pflueger & Ringer	Review/ (ongoing)
2018	La Follette, Johnson, DeHaas, Fesler & Ames	Review/Opinion/Deposition
2018	David L. Hunter	Review
2013	Virginia C. Nelson	Review

ATTACHMENT C

CONFIDENTIAL - PURSUANT TO PROTECTIVE ORDER

ROBERT A. MINKIN, FACHE

[REDACTED] | Email: robertm257@outlook.com

PROFESSIONAL SUMMARY

A servant leader with more than 30 years of intentional, focused performance to create organizational excellence through effective strategic planning, organizational right-sizing, world class management team development, active business and opportunity development, physician group expansion and Board development. Those who have served with me describe me as a visionary leader who integrates the Mission and Vision of the organization into purpose and action.

RELEVANT EXPERIENCE

COPE HEALTH SOLUTIONS, INC.*Principal*

Los Angeles, CA

04/2019 - Present

Retained to lead and develop the west coast client base for consulting and analytics platforms—8 consultants reporting to my role.

INDEPENDENT HEALTHCARE ADVISOR AND CONSULTANT

11/2017 - 04/2019

EDUCATIONAL SABBATICAL—INTERNATIONAL HEALTHCARE MODELS

02/2017 - 10/2017

O'CONNOR & ST. LOUISE REGIONAL HOSPITALS*Market President & Chief Executive Officer*

San Jose, CA

09/2015 – 11/2016

Undertook turnaround responsibility at two separately licensed acute care facilities and a Medical Foundation with 85 physicians 30 miles apart totaling 467 beds in San Jose and Gilroy, California at the change of ownership from Daughters of Charity to Verity Healthcare. Initial budget plans on taking market's financial results from a \$35M loss to a breakeven in 12 months of operation.

- Rebuild both hospital's Executive teams and installed operational rigor to position both organizations for success
- Rebuilt Governance structures consistent with Attorney Generals Conditions of operation
- Renegotiated major managed care plans arrangements to improve PCR
- Adjusted all labor and non-labor expenses to best in class benchmark levels
- Developed/began implementation of key service line reinvestment plan
- Developed exclusive healthcare sponsor/provider relationship with San Jose State University
- Redeveloped Quality and Value scorecards and goals
- YTD through Sept results ahead of plan

THE CAMDEN GROUP*Senior Vice President*

El Segundo, CA

06/2010 – 07/2015

- Specializing in all forms of Hospital/Health system consulting/advisory/implementation services inclusive of hospital efficiency and value development with payers;
- Significant consultations in Clinical Co-management, clinical Service line development, inclusive of
- ACO and Bundled Payment readiness and implementation engagements.
- Promoted to **Hospital Operations Practice Leader** in 2012 with 15 consultants reporting across 5 offices nationally.
- Developed Pre/Post Merger consolidation/ Integration planning
- Developed Implementation services to firm consulting scope.
- Typical projects focus upon using clinical service lines in single or multiple entities within a Health System to drive Value development.
- Served 200 + clients over the last 4 years with \$16M in sales.
- Client listing upon request.

EXEMPLA SAINT JOSEPH HOSPITAL (SCLHS SPONSORED)*President & Chief Executive Officer*

Denver, CO

06/2006 – 01/2010

ESJH is a 135-year-old, religiously sponsored 565-bed tertiary teaching medical center; \$450 million in net revenues with 2500 FTEs and 1200 Medical Staff. ESJH is the key regional tertiary partner to Kaiser Permanente Health Plan and Permanente Medical Group through a unique co-management relationship; anchor Hospital to the Exempla/SCLHS System.

Key accomplishments include:

- Achieved COE status with United, Kaiser and other major health plans for major clinical service lines using Physician/Hospital Bundling as a differentiator resulting in volume and market share increases;
- Execution of JV with Denver's largest group of community Cardiologists to create a co-managed Cardiac and Vascular Institute; One of four hospitals nationally to qualify for the Cardiac ACE Demonstration project with CMS; achieved 99th percentile clinical performance; grew volumes 20%;
- Executed an ESJH based MSO for community Physicians to join as an initial integration strategy;
- Closed a failed Orthopedic Specialty Hospital JV losing \$12 M/yr.;
- Rebuilt organizational culture around safety, service and satisfaction;
- Implemented EPIC Electronic Medical Record for inpatient and Ambulatory use;
- Co-Led cross System Operations Counsel to identify and implement supply savings through third party vendor consolidation. Grew collaboration scope to extend Faculty to each Exempla Hospital;
- Implemented fully integrated 'Plane Tree light' care concept on three inpatient units
- Implemented ESJH's first Comprehensive Cancer center with 15 employed (via PSA's) physicians;
- Achieved 5-year RRC accreditation for all segments of the teaching program, 3-year JCAHO Accreditation;
- Initiated Bariatric and Robotic surgery programs;
- Achieved 90th percentile or better clinical results in all Medicare Core Measures;
- Achieved a 17% EBITDA; 6 % Income.

ST. JOSEPH HOSPITAL (SJHS SPONSORED)*Executive Vice President & Chief Operating Officer*

Orange, CA

1998 - 2006

Responsible for a 120-year-old, \$420 million, 448-bed tertiary medical center's daily operations and strategy development, the anchor facility for a four-hospital regional cluster serving the needs of 250,000 managed care lives in an integrated system (Medical Foundation) model. Grew net revenues by 40% to \$520 million over tenure. SJO had provided all clinical and ancillary support services to an adjoining freestanding 200 bed Children's Hospital during my tenure.

Key accomplishments include:

- Upon entering my role, led a "Operations Redesign" effort that reduced more than \$25 million from the facility's cost base improving performance from a \$10 million deficit to a \$19 million positive contribution margin;
- Led the creation of a Comprehensive Cancer Center with 3 independent Oncology Groups, combining separate Infusion operations into one, built a 240,000-sf building to house a one stop patient experience as a joint venture with participating MD's and a real estate development company;
- First Catholic Hospital in Calif. to achieved ANA 'Magnet' status after 5 years of sustained effort;
- Implemented a Medical Staff development plan that recruited new medical talent to existing practices, mainly in the Surgical subspecialties resulting in achieving the largest single hospital surgical market share in Calif.;
- Through a management restructuring, reset operational culture to ultimately turn the organization into the Income and Quality leader within the Health System.
- Despite many attempts by bargaining groups, this entity was non-union well after my tenure and an example of open collaboration with all constituencies.
- Extended Clinical program to surrounding sister hospitals where opportunities allowed

DESERT HOSPITAL CORPORATION (DISTRICT & TENET SPONSORED)*President/CEO**Executive Vice President of Ambulatory Services*

Palm Springs, CA

1993 – 1998

1992 - 1993

Led the strategic effort for the Board that resulted in a successful affiliation of our \$250 million, 398-bed tertiary district hospital with a major for-profit healthcare system (Tenet). Grew earnings to more than \$20 million in year one following the affiliation and with \$25 million in year two.

Key Accomplishments:

- Resolved long standing conflict between Board and Medical Staff through effective communication and trust building;
- Converted a 150,000-sf failed 'condo' medical office building into a full-service ambulatory center; new services included a Comprehensive Cancer Center, an Ambulatory Surgery, a Pain Management Service and an Imaging Center.
- Rented over 80,000 square feet for Physician's offices from the community.
- Established a true service culture resulting in top rankings within the Tenet organization for Patient, Physician and Employee satisfaction;
- Through trust building with staff, was able to sustain an "open shop" union contract with the CNA resulting in less than 50 dues paying employees out of 850 eligible;
- Developed a hospital-based capitation strategy with the area's major IPA resulting in exclusive contracting.

SANTA ROSA HEALTHCARE CORPORATION (SICW SPONSORED)

San Antonio, TX

Interim Corporate Chief Operating Officer

1991 - 1992

Provided Interim management services to a \$400 million not for profit, six-hospital Catholic-sponsored system, including a regional children's hospital.

Key Accomplishments:

- Implemented a management reorganization which improved net profitability from \$8 million to \$10 million in nine months;
- Implemented a system wide labor productivity management system and the discipline to meet its requirements daily.

THE HUNTER GROUP (PROPRIETARY)

Point Vedra, FL

Senior Operations Consultant

1991 - 1992

- Functioned as an operations/turnaround consultant for the most successful troubled hospital turnaround company in the United States.
- Participated in or lead teams in over 25 engagements which included outcomes as described below;
- Orchestrated the sale of a failing Catholic hospital within six weeks following an aggressive review and implementation of a turnaround strategy that prevented closure of the facility;
- Led the turnaround of a major-medical center from a \$9 million loss to a \$7 million positive margin in one year through replacement of the leadership team and ongoing operations management; *Provided similar services to many other similar situations in healthcare with clients all over the US.

RIVERSIDE COMMUNITY HOSPITAL (PRIVATE COMMUNITY SPONSORED)

Riverside, CA

Chief Operating Officer & President of Riverside Community Ventures Corp.

1987 - 1991

Responsible for the total operations of a 445-bed tertiary care hospital with revenues in excess of \$200 million. Directed patient care services, finance, facilities, human resources and centers of specialty including cardiology, orthopedics, trauma, women's health and neonatal intensive care. Directed a \$28 million group of health venture companies including surgery centers, imaging centers, three family practice clinics, a 70-bed psychiatric hospital and a managed care company covering 450,000 lives.

Key Accomplishments:

- Implemented service line management structures to capitalize on quality and market share opportunities;
- Reorganized management and staffing structures to respond to the negative effects of managed care;
- Opened a JV Surgery Center with 28 MD Investors;
- Improved the performance of the Ventures Company from a \$4 million loss to a \$3 million income in 18 months.

CONFIDENTIAL - PURSUANT TO PROTECTIVE ORDER**MEMORIAL HOSPITAL ASSOCIATION (PRIVATE COMMUNITY SPONSORED)****Senior Vice President, Operations/Hospital Administrator**

Modesto, CA

1980 - 1987

Directed daily operations and professional ancillary services for a 192-bed tertiary care facility at Modesto and at the 122-bed general acute care facility at Ceres served as Administrator with combined revenues of \$92 million. Simultaneously served as contract Administrator for a 22-bed district hospital (Westside Community Hospital).

Key Accomplishments:

- Improved Community and Physician perception of Memorial-Ceres by increasing service and performance across the medical spectrum;
- Partnered with the Gould Medical Foundation in providing outpatient care to Capitated patients;
- Grew Radiation therapy and Imaging volumes through JV's with Community Physicians.

EDUCATION

CAMDEN LEADERSHIP ACADEMY

2014

MINISTRY LEADERSHIP FOMATION

2004

CALIFORNIA STATE UNIVERSITY, SAN FRANCISCO

San Francisco, CA

Master of Business Administration

1980

ADMINISTRATIVE RESIDENCY, COMMUNITY HOSPITAL SANTA ROSA

Santa Rosa, CA

Sponsored by UCSF

1975-1976

CALIFORNIA STATE UNIVERSITY, SONOMA

Sonoma, CA

Bachelor of Science

1975

ADDITIONAL INFORMATION

PROFESSIONAL/COMMUNITY SUPPORT ACTIVITIES

American College of Hospital Executives, FACHE (2011)

St. Joseph Health System, Investment Sub-Committee Member

United Way of Orange County, Allocations Committee Member

Healthcare Association of Southern California (HASC), Finance Committee Member

Saddleback Church Volunteer

Board Member, Arch Medical Group/ACO

EXHIBIT 10

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

PAR PHARMACEUTICAL, INC.,)	
PAR STERILE PRODUCTS, LLC, and)	
ENDO PAR INNOVATION)	
COMPANY, LLC,)	
)	C.A. No. 18-823-CFC
Plaintiffs,)	
)	
v.)	
)	
EAGLE PHARMACEUTICALS INC.,)	
)	
Defendant.)	

DEFENDANT'S WITNESS LIST

Pursuant to Local Rule 16.3(c), Eagle identifies the following witnesses whom Eagle intends to or may call live or by deposition at trial. This list is not a commitment that Eagle will call any particular witness at trial, or a representation that any of the witnesses listed are available or will appear for trial. By identifying these witnesses, Eagle is not required to call any listed witness at trial, nor is Eagle limited in the manner in which such testimony is presented at trial. With respect to Plaintiffs' witnesses, Eagle reserves the right to introduce testimony through deposition or live examination, as appropriate or by agreement. Eagle also reserves the right to call any witnesses called by Plaintiffs or anyone currently or formerly employed by or for Plaintiffs appearing on Plaintiffs' witness list, and to revise this list in light of further rulings by the Court or any other changed circumstances. Eagle further reserves the right to call one or more additional witnesses to provide foundational testimony to establish the authenticity or admissibility of any material proffered at trial if the admissibility or authenticity is challenged by Plaintiffs. Eagle also reserves the right to call any witness for impeachment purposes. Eagle reserves the right to further modify, supplement, and/or amend the Final Pretrial Order and attachments in light of issues that remain open and until entry of the Final Pretrial Order.

I. EXPERT WITNESSES

Below are the expert witnesses Eagle intends to call live at trial. The curriculum vitae for each expert is also attached herein.

- (i) Mansoor M. Amiji, Ph.D., R.Ph. (CV included as Attachment A hereto)
- (ii) Leonard P. Chyall, Ph.D. (CV included as Attachment B hereto)
- (iii) Carmen Cross, M.D. (CV included as Attachment C hereto)
- (iv) Kinam Park, Ph.D. (CV included as Attachment D hereto)

II. FACT WITNESSES

Below are the fact witnesses that Eagle may call at trial live or by deposition (as indicated).

- (i) Ronald Aungst (live or by deposition)
- (ii) Brian Boesch (deposition)
- (iii) Michelle Bonomi-Huvala (deposition)
- (iv) Carla English (deposition)
- (v) Adrian Hepner (live)
- (vi) Vinayagam Kannan (live or by deposition)
- (vii) Craig Kenesky (deposition)
- (viii) Matthew Kenney (deposition)
- (ix) Michelle Rennwald (deposition)
- (x) James Romito (live)
- (xi) Suketu Sanghvi (live or by deposition)

EXHIBIT 10

(xii) Sunil Vandse (live or by deposition)

Attachment A

CURRICULUM VITAE

MANSOOR M. AMIJI, PhD, RPh

CONTACT INFORMATION

Office Address:

Northeastern University



E-mail: m.amiji@northeastern.edu

Website: <http://www.northeastern.edu/amijilab>

Home Address:



EDUCATION AND TRAINING

September, 1984 - June, 1988: Undergraduate Student in the College of Pharmacy and Allied Health Professions, Northeastern University, Boston, MA.

September, 1986 - May, 1988: Undergraduate Honors Student Research Project Entitled "*Preparation and Characterization of Doxorubicin-Dextran Conjugates*" – Major Advisor: Professor Mehdi Boroujerdi.

June, 1988: Bachelor of Science in Pharmacy (*magna cum laude*).

August, 1988 - July, 1992: Doctoral Student in the Department of Industrial and Physical Pharmacy, College of Pharmacy, Purdue University, West Lafayette, Indiana.

August, 1988 - June, 1989: Teaching Assistant in the Department of Industrial and Physical Pharmacy.

July, 1989 - June, 1992: Research Assistant in the Department of Industrial and Physical Pharmacy.

July, 1989 - June, 1992: Doctoral Dissertation Research Entitled "*Surface Modification of Biomaterials with Water-Soluble Polymers: A Steric Repulsion Approach*" - Major Advisor: Professor Kinam Park.

July, 1992: Doctor of Philosophy in Pharmaceutical Science/Pharmaceutics.

PROFESSIONAL AND ACADEMIC POSITIONS

August, 1992 – December, 1992: Senior Research Scientist, Columbia Research Laboratories, Madison, WI.

January, 1993 – June, 1999: Assistant Professor, Department of Pharmaceutical Sciences, School of Pharmacy, Northeastern University, Boston, MA.

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July, 1999 – April, 2006: Associate Professor (with tenure), Department of Pharmaceutical Sciences, School of Pharmacy, Northeastern University, Boston, MA.

June, 2000 – December, 2000: Visiting Research Scholar. Department of Chemical Engineering, MA Institute of Technology, Cambridge, MA. (Sabbatical leave appointment in Institute Professor Robert Langer's group).

May, 2006 – Present: Full Professor, Department of Pharmaceutical Sciences, School of Pharmacy, Northeastern University, Boston, MA.

February, 2010 – April, 2016: Bouve College Distinguished Professor, Department of Pharmaceutical Sciences, School of Pharmacy, Northeastern University, Boston, MA.

September, 2012 – July, 2018: Affiliate Faculty Member, Department of Chemical Engineering, College of Engineering, Northeastern University, Boston, MA.

September, 2013 – Present: Affiliate Faculty Member, Department of Biomedical Engineering, College of Engineering, Northeastern University, Boston, MA.

January, 2014 – September, 2017: Distinguished Adjunct Professor, Faculty of Pharmacy, King Abdulaziz University, Jeddah, Saudi Arabia.

April, 2016 – Present: University Distinguished Professor, Department of Pharmaceutical Sciences, School of Pharmacy, Northeastern University, Boston, MA.

March, 2017 – August, 2018: Distinguished Adjunct Professor, Institute for Research and Medical Consultation (IRMC), Imam Abdulrahman bin Faisal University, Dammam, Saudi Arabia.

August 2018 – Present: Professor. Department of Chemical Engineering, College of Engineering, Northeastern University, Boston, MA.

ADMINISTRATIVE AND LEADERSHIP POSITIONS

July, 1995 – June 2000: Pharmaceutics Group Leader, Department of Pharmaceutical Sciences, School of Pharmacy at Northeastern University, Boston, MA.

September, 2002 – June, 2004: Education and Outreach Coordinator, Molecular Biotechnology Initiative at Northeastern University, Boston, MA.

July 2003 – Present: Co-Director, Nanomedicine Education and Research Consortium (NERC) at Northeastern University, Boston, MA.

July, 2005 – December, 2008: Associate Chairman, Department of Pharmaceutical Sciences, School of Pharmacy at Northeastern University, Boston, MA.

January, 2009 – January, 2010: Interim Chairman, Department of Pharmaceutical Sciences, School of Pharmacy at Northeastern University, Boston, MA.

Page

February, 2010 – April, 2016: Chairman, Department of Pharmaceutical Sciences, School of Pharmacy, Northeastern University, Boston, MA.

RESEARCH INTERESTS

The primary focus of research in my laboratory is on the development of biocompatible materials from natural and synthetic polymers, target-specific drug and gene delivery systems for cancer and infectious diseases, and nanotechnology applications for medical diagnosis, imaging, and therapy. Specific projects that we are currently pursuing include:

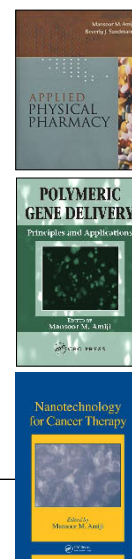
- Synthesis of novel polymeric materials for medical and pharmaceutical applications.
- Preparation and characterization of polymeric membranes and microcapsules with controlled permeability properties for medical and pharmaceutical applications.
- Target-specific drug, gene, and vaccine delivery systems for diseases of the gastro-intestinal tract.
- Delivery of DNA and siRNA to mucosal surfaces for gene therapy and vaccination.
- Localized delivery of cytotoxic and anti-angiogenic drugs, siRNA, and genes for solid tumors in novel biodegradable polymeric nanoparticles.
- Intracellular and sub-cellular delivery systems for drugs and genes using target-specific, long-circulating, biodegradable polymeric nanoparticles.
- Role of hypoxia and tumor microenvironment in development of tumor drug resistance, angiogenesis, and metastasis.
- Local administration of drugs and nucleic acid-containing nanovectors immobilized on stents for the treatment of arterial diseases (e.g., coronary restenosis).
- Novel oil-in-water nanoemulsion formulations for drug delivery through the gastrointestinal tract and across the blood-brain barrier.
- Systemic and mucosal vaccination using novel immune-modulatory strategies and delivery systems.
- Intranasal administration of liposomes and nanoemulsions to enhance brain delivery of peptides, proteins, siRNA, and genes.
- Functionalized inorganic nanoparticles - including gold, iron oxide, alloys, and core-shell nanostructures - for biosensing, imaging, and targeted therapeutic applications.

PUBLICATIONS [Google Scholar Hirsch “h” index = 85] – Highly Cited Researcher (Top 1%) in Pharmacology & Toxicology

Book Editorship

Amiji, M.M. and Sandmann, B.J. (eds.). *Applied Physical Pharmacy*. Published by McGraw-Hill Medical Publishing Division. New York, NY. 2002.

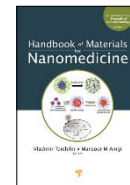
Amiji, M.M. (ed.) *Polymeric Gene Delivery: Principles and Applications*. Published by CRC Press, LLC (a subsidiary of Taylor and Francis). Boca Raton, FL. 2004.



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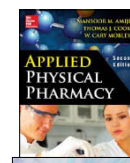
Amiji, M.M. (ed.). *Nanotechnology for Cancer Therapy*. Published by CRC Press, LLC (a subsidiary of Taylor and Francis). Boca Raton, FL. 2007.

Torchilin, V.P. and **Amiji, M.M.** (eds.). *Handbook of Materials for Nanomedicine*. Publication of the *Biomedical Nanotechnology Series*, (10 Volumes Book Series edited by Torchilin, V.P. and **Amiji, M.M.**). Volume 1, Published by Stanford Publishing, Singapore, 2010.

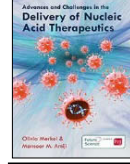


Amiji, M.M., Cook, T., and Mobley, W.C. (eds.). *Applied Physical Pharmacy – Second Edition*. Published by McGraw-Hill Medical Publishing Division. New York, NY, 2014.

Merkel, O.M. and **Amiji, M.M.** (eds.). *Advances and Challenges in the Delivery of Nucleic Acid Therapeutics – Volumes 1 and 2*. E-Books Published by Future Science, LTD, London, UK. 2015. <http://www.futuremedicine.com/doi/book/10.4155/9781910419922>.



Milane, L.S. and **Amiji, M.M.** (eds.). *Nanomedicine for Inflammatory Diseases*. Published by CRC Press, LLC (a subsidiary of Taylor and Francis). Boca Raton, FL. 2017.

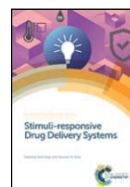


Singh, A and **Amiji, M.M.** (eds.). *Stimuli-Responsive Drug Delivery Systems*. Royal Society of Chemistry Biomaterial Series Publication. Royal Society of Chemistry, London, UK. 2018



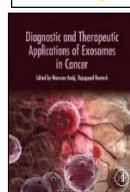
Amiji, M.M. and Ramesh, R. (eds.). *Diagnostic and Therapeutic Applications of Exosomes in Cancer*. Elsevier Publishing Company. San Diego, CA. 2018.

Mobley, W.C., **Amiji, M.M.**, and Cook, T., (eds.). *Applied Physical Pharmacy – Third Edition*. Published by McGraw-Hill Medical Publishing Division. New York, NY, 2019.

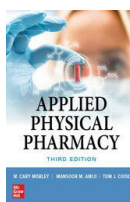


Book Chapters

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Jain, S. and **Amiji, M.** Non-condensing calcium alginate microspheres for macrophage-selective gene delivery and transfection. *Proceedings of the NSTI Nanotech 2008, NSTI Nanotechnology Conference and Trade Show*, Boston, MA June 1-5, (2008).

Pai, S. and **Amiji, M.** Multifunctional nanoparticulate system for simultaneous *EGFR* gene silencing and enhancement of apoptosis in pancreatic cancer cells. *Proceedings of the NSTI Nanotech 2008, NSTI Nanotechnology Conference and Trade Show*, Boston, MA June 1-5, (2008).

Brito, L., Chandrasekhar, C., Little, S.R., and **Amiji, M.M.** Gene delivery and transfection studies in smooth muscle cells with lipopolyplexes immobilized in gelatin-coated stainless steel substrates. *Proceedings of the International Symposium on the Controlled Release of Bioactive Materials* (2008).

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- Milane, L., Matthäus, C., Chernenko T., Diem, M., and **Amiji, M.** Cellular trafficking studies of ceramide-loaded poly(ethylene oxide)-modified poly(epsilon-caprolactone) nanoparticles with Raman spectroscopy. *Proceedings of the International Symposium on the Controlled Release of Bioactive Materials* (2008).
- Magadala, P. and **Amiji, M.M.** Epidermal growth factor receptor-targeted gelatin-based nanoparticles for reporter and therapeutic gene delivery in human pancreatic cancer cells. *The AAPS Journal*, **10**: S2, (2008).
- Deshpande, D. and **Amiji, M.** *In vitro* studies with estradiol-loaded omega-3 fatty acid-containing oil-in-water nanoemulsion formulations for the treatment of coronary restenosis. *The AAPS Journal*, **11**: S2, (2009).
- Ganta, S., Devalapally, H., and **Amiji, M.** The effect of curcumin in enhancing oral absorption and anti-tumor therapeutic efficacy of paclitaxel administered in nanoemulsion formulations. *The AAPS Journal*, **11**: S2, (2009).
- Kriegel, C. and **Amiji, M.** TNF α gene silencing using nanoparticles-in-microsphere oral delivery system in an inflammatory bowel disease model. *The AAPS Journal*, **11**: S2, (2009).
- Jain, S. and **Amiji, M.M.** Tuftsin-modified alginate nanoparticles as a non-condensing macrophage-targeted gene delivery system for anti-inflammatory therapy. *Proceeding of the International Symposium on the Controlled Release of Bioactive Materials* (2010).
- Deshpande, D. and **Amiji, M.M.** Preliminary evaluations of combination ceramide/estradiol therapy in coronary restenosis with omega-3 fatty acid-containing nanoemulsion formulations. *Proceeding of the International Symposium on the Controlled Release of Bioactive Materials* (2010).
- Attarwala, H. and **Amiji, M.M.** *In vitro* evaluations of nanoparticle-in-emulsion formulations for gene delivery and transfection in macrophages. *Proceeding of the International Symposium on the Controlled Release of Bioactive Materials* (2010).
- Deshpande, D. and **Amiji, M.M.** Preliminary evaluations of combination ceramide/estradiol therapy in atherosclerosis with omega-3 fatty acid-containing nanoemulsion formulations. *The AAPS Journal*, **12**: S2, (2010).
- Jain, S. and **Amiji, M.M.** Tuftsin-modified alginate nanoparticles as a non-condensing macrophage-targeted gene delivery system for anti-inflammatory therapy. *The AAPS Journal*, **12**: S2, (2010).
- Barchet, T. and **Amiji, M.M.** Advances in siRNA delivery: preliminary work in the development of an siRNA nanoemulsion delivery system. *The AAPS Journal*, **12**: S2, (2010).
- Xu, J. and **Amiji, M.M.** Gene delivery and transfection in human pancreatic cancer cells using epidermal growth factor receptor-targeted gelatin nanoparticles. *The AAPS Journal*, **12**: S2, (2010).

INTRAMURAL AND EXTRAMURAL RESEARCH SUPPORT (Total = \$40M; as PI = \$30M)

Current Funding

Page

Source: National Institute of Diabetes, and Digestive Diseases, and Kidney Diseases (NIDDK) of the National Institutes of Health.

Title: Heat Shock Protein 90 in Alcoholic Liver Disease: Targeting Macrophage Function

Amount: \$1,570,350 (total), NU Share: \$75,000

Duration: August, 2015 – July, 2020

Role: PI of NU Sub-Contract (PI: Pranoti Mandrekar, University of Massachusetts Medical School, Worcester, MA)

Source: Glaxo-Smith Kline Vaccines, Cambridge, MA

Title: Pharm Sci Industrial Graduate Fellowship Program (designated to Mr. Rushit Lodaya)

Amount: \$195,000 (total)

Duration: October, 2015 – December, 2019

Role: Principal Investigator

Source: Dicerna Pharmaceuticals, Inc. Cambridge, MA

Title: Pharm Sci Industrial Graduate Fellowship Program (designated to Ms. Dongyu Chen)

Amount: \$195,000 (total)

Duration: October, 2015 – December, 2019

Role: Principal Investigator

Source: National Cancer Institute of the National Institutes of Health, R21 Proposal in response to PAR13-146 "NCI Exploratory/Developmental Research Grant Program (NCI Omnibus R21)". (R21 proposal CA213114-01A1).

Title: Reprogramming Tumor-Associated Macrophages in PDAC with MicroRNA Nano-Vectors

Amount: \$427,625 (total)

Duration: August, 2017 – July, 2020 (with NCE)

Role: Multi-Principal Investigator (with Prof. Gerardo Mackenzie, University of California at Davis, Davis, CA)

Source: National Institute of Neurological Disorders and Stroke, National Institutes of Health R01 Grant (R01-NS108968) Sub-contract from Massachusetts Eye and Ear Infirmary

Title: Direct CNS Delivery System for BDNF Antagonists using Heterotopic Mucosal Grafting for the Treatment of Parkinson's Disease

Amount: \$2,546,316 (total); NU Sub-contract: \$1,279,394

Duration: January, 2019-December, 2023

Role: Principal Investigator on NU Sub-Contract (PI of the Grant: Dr. Benjamin Bleier)

Source: National Institutes of Health, Office of the Director (R21-OD027052-01)

Sub-contract from Jackson Laboratory, Inc.

Title: Development and Validation of a Novel Cas13a and Nanoparticle Guide-RNA Delivery System that Allows Precise Ablation of Host Macrophage Populations in a Humanized Mouse Model

Amount: \$475,000 (total); NU Sub-contract: \$65,000

Duration: April, 2019 – March, 2021

Role: Principal Investigator on NU Sub-Contract (PI of the Grant: Dr. Michael Wiles)

Source: Takeda Vaccines, Cambridge, MA

Title: Academic-Industrial Post-Doctoral Fellowship

Amount: \$181,657

Duration: August, 2019 – July, 2021

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Role: Principal Investigator on NU Sub-Contract (PI of the Grant: Dr. Michael Wiles)

Past Funding

Source: National Institutes of Health, Biomedical Research Support Grant

Title: Prevention of Protein Adsorption on Poly(Ethylene Oxide)-Modified Surfaces

Amount: \$2,000 (total).

Duration: June, 1993 - May, 1994

Role: Principal Investigator

Source: Northeastern University, 1995 Research and Scholarship Development Fund

Title: Development of Blood-Compatible Hemodialysis Membranes from Chitosan

Amount: \$10,000 (total)

Duration: July, 1995 - December, 1996 (with 6-months no-cost extension)

Role: Principal Investigator

Source: Bristol-Myers Squibb Pharmaceutical Research Institute, Kenilworth, NJ.

Title: Development of Novel Thermogelling System for Localized Delivery of Taxol®

Amount: \$8,000 (total)

Duration: July, 1996 - June, 1997

Role: Principal Investigator.

Source: Roche Laboratories, Inc., Nutley, NJ.

Title: HPLC Assay Development for Mycophenolic Acid and Mycophenolic Acid Glucuronide

Amount: \$10,000 (total)

Duration: July 1996 - December, 1996

Role: Co-Principal Investigator (PI: Prof. Rafaat Seifeldin, Department of Pharmacy Practice, Northeastern University)

Source: Northeastern University, Honors Program Research Funds

Title: Undergraduate Honors Students Research Initiatives

Amount: \$5,000.

Duration: July 1997 - June 1999.

Role: Principal Investigator.

Source: Pharmaceutical Research and Manufacturers of America Foundation, Undergraduate Pharmaceutics Research Fellowship. (On behalf of Ms. Phung-Kim Lai, B.S. student in the class of 1999).

Title: Novel Thermogelling Paclitaxel Formulation for Intra-Tumoral Delivery

Amount: \$5,000 (total)

Duration: January, 1999 - December, 1999

Role: Principal Investigator.

Source: Northeastern University, 1999 Research and Scholarship Development Fund

Title: Stomach-Specific Antibiotic Delivery for *H. pylori* Infection

Amount: \$10,000 (total)

Duration: July, 1999 - June, 2000

Role: Principal Investigator

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Source: EOS Pharmaceuticals Corporation, Woburn, MA (through National Institutes of Health, Small Business Innovation Research Program, Phase I Grant)

Title: Stomach-Specific Anti-*H. pylori* Therapy

Amount: \$50,000 (total, ~ 45% of the total SBIR funding)

Duration: July, 2000 – June, 2001

Role: Principal Investigator

Source: American Association of Pharmaceutical Scientists and American Foundation for Pharmaceutical Education, 2000-2001 “Gateway” Research Scholar Program. (On behalf of Mr. Chi-Sing Nip, Pharm.D. student, Class of 2001)

Title: Perm-selective Membranes from Chitosan for Extracorporeal Removal of β -2-Microglobulin

Amount: \$5,000 (total)

Duration: July, 2000 – June, 2001

Role: Principal Investigator

Source: Braintree Laboratories, Inc., Braintree, MA

Title: Analysis of Phosphate Binding to Cationic Polymers

Amount: \$31,000 (total)

Duration: December, 2000 – June, 2001

Role: Principal Investigator

Source: Pharmaceutical Research and Manufacturers of America Foundation, Undergraduate Pharmaceutics Research Fellowship. (On behalf of Ms. Erica J. Waugh, Pharm.D. student in the class of 2002)

Title: Novel Biodegradable Long-Circulating Nanoparticles for Tumor-Selective Drug Delivery

Amount: \$5,000 (total)

Duration: January, 2001 – December, 2001

Role: Principal Investigator

Source: Braintree Laboratories, Inc., Braintree, MA

Title: Chitosan-Iron Complexes as Polymeric Phosphate Binders

Amount: \$15,000 (total)

Duration: January, 2002 – June, 2002

Role: Principal Investigator

Source: Northeastern University, Undergraduate Research Fund. (On behalf of Ms. Nikita Mody, Pharm.D. student in the class of 2004)

Title: Tumor-Selective Gene Delivery Systems

Amount: \$3,000 (total)

Duration: January, 2002 – June, 2002

Role: Principal Investigator

Source: Northeastern University, 2002 Research and Scholarship Development Fund

Title: Immobilized Enzyme System for Detection and Detoxification of Chemical Warfare Agents

Amount: \$5,006 (total)

Duration: July, 2002 - June, 2003

Role: Principal Investigator

Source: Alfred P. Sloan Foundation, New York, NY

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Title: Multi-Track Professional Masters Degree Program in Biotechnology

Amount: \$75,000 (total)

Duration: July, 2002 – June 2004 (with one year no-cost extension)

Role: Co-Investigator (PI: Prof. William Detrich, Department of Biology, Northeastern University).

Source: Boston Scientific Corporation. Watertown, MA

Title: Drug Interactions with Poly(vinyl alcohol) Embolic Microspheres: Part I

Amount: \$33,256 (total)

Duration: February, 2003 – December, 2003

Role: Principal Investigator

Source: National Cancer Institute, National Institutes of Health (R01-CA95522-01A2)

Title: Long-Circulating Tumor-Selective DNA Delivery Systems

Amount: \$744,100 (total)

Duration: July, 2003 – June, 2007* (with one-year no-cost extension)

Role: Principal Investigator

Source: National Science Foundation, Major Research Instrumentation Grant (MRI-0320638)

Title: Acquisition of Scanning Electron Microscope for Nanoscience and Biotechnology

Amount: \$477,846 (total)

Duration: July, 2003 – June, 2004

Role: Co-Investigator (PI: Prof. Donald Heiman, Department of Physics, Northeastern University)

Source: Roger Williams Medical Center, Providence, RI. Subcontract of the Department of Defense Grant DAMD17-03-0716

Title: Drug Encapsulation in Poly(Epsilon-Caprolactone) Nanoparticles

Amount: \$20,119 (total)

Duration: October, 2003 – September, 2005 (with one year no-cost extension)

Role: Principal Investigator

Source: Boston Scientific Corporation. Watertown, MA

Title: Drug Interactions with Poly(vinyl alcohol) Embolic Microspheres: Part II

Amount: \$44,865 (total)

Duration: February, 2004 – December, 2004

Role: Principal Investigator

Source: American Foundation for Pharmaceutical Education, Undergraduate Gateway Research Scholarship. (On Behalf of Ms. Stephanie Whalen, PharmD Class of 2006)

Title: Novel Gold Nanoparticle Sensor for Non-invasive Glucose Measurements

Amount: \$5,000 (total)

Duration: June, 2004 – December, 2004

Role: Principal Investigator

Source: Boston Scientific Corporation, Natick, MA

Title: Preparation and Characterization of Drug-Loaded SIBS Copolymer Microsphere Formulations

Amount: \$100,019 (total)

Duration: October, 2004 – December, 2005 (with no-cost extension)

Role: Principal Investigator

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Source: Novavax, Inc., Malvern, PA.

Title: Nanocarrier Formulation Optimization Studies

Amount: \$60,543 (total)

Duration: May, 2005 – December, 2005

Role: Principal Investigator

Source: American Foundation for Pharmaceutical Education, Undergraduate Gateway Research Scholarship. (On Behalf of Mr. Zeu Hong Tzeng, PharmD Class of 2007)

Title: Thiolated Gelatin Nanoparticles for Intracellular siRNA Delivery

Amount: \$5,000 (total)

Duration: July, 2005 – June, 2006

Role: Principal Investigator

Source: Northeastern University, 2005 Research and Scholarship Fund

Title: Functionalized Gold Nanoparticles as Novel Mitochondria-Targeted Vectors

Amount: \$15,000 (total)

Duration: July, 2005 – June, 2006

Role: Co-Investigator (PI: Prof. Volkmar Weissig, Department of Pharmaceutical Sciences, Northeastern University)

Source: Transport Pharmaceuticals, Inc., Framingham, MA

Title: Evaluation of Formulation Properties Used in Iontophoretic Drug Delivery Device

Amount: \$58,875 (total)

Duration: August, 2005 – July, 2006

Role: Principal Investigator

Source: Boston Scientific Corporation. Marlborough, MA

Title: Drug Interactions with Poly(vinyl alcohol) Embolic Microspheres: Part III

Amount: \$125,208 (total)

Duration: March, 2006 – February, 2007

Role: Principal Investigator

Source: Transport Pharmaceuticals, Inc., Framingham, MA

Title: Evaluation of Formulation Properties Used in Iontophoretic Drug Delivery Device: Part II

Amount: \$72,952 (total)

Duration: August, 2006 – July, 2007

Role: Principal Investigator

Source: Parsalus Pharmaceuticals, Inc., Boston, MA

Title: Preliminary Micellar Characterization Studies of Lipopeptide Molecules

Amount: \$12,372 (total)

Duration: October, 2007 – January, 2008

Role: Principal Investigator

Source: The Michael J. Fox Foundation for Parkinson's Research

Title: Feasibility of Intranasal Delivery of GDNF for Parkinson's Disease

Amount: \$74,800 (total)

Duration: November, 2007 – December, 2008

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Role: Co-Investigator (PI: Prof. Barbara Waszczak, Department of Pharmaceutical Sciences, Northeastern University)

Source: Microfluidics, Inc., Newton, MA

Title: HPLC Studies of Drug Encapsulation in Polymeric Nanoparticle Formulations

Amount: \$13,549 (total)

Duration: May, 2008 – July, 2008

Role: Principal Investigator

Source: BioCure, Inc., Norcross, GA

Title: Cellular Uptake and Trafficking Properties of siRNA-Loaded Polymeric Nano-Vesicles

Amount: \$28,414 (total)

Duration: July, 2008 – June, 2009

Role: Principal Investigator

Source: National Cancer Institute of the National Institutes of Health, Nanotechnology Characterization Laboratory, Frederick, MD.

Title: Multifunctional Nanoemulsions for Brain Tumor Imaging and Therapy

Amount: Undisclosed (complete preclinical characterization studies)

Duration: July, 2006 – December, 2009

Role: Principal Investigator

Source: National Cancer Institute of the National Institutes of Health, Nanotechnology Characterization Laboratory, Frederick, MD.

Title: Engineered Gelatin-Based Nanovectors for Pancreatic Cancer Gene Therapy

Amount: Undisclosed (complete preclinical characterization studies)

Duration: July, 2007 – December, 2009

Role: Principal Investigator

Source: Physical Sciences, Inc., Andover, MA. Sub-Contract of the National Cancer Institute STTR Phase I Application in response to RFA “*Image Guided Cancer Interventions*” (STTR R41/R42) (1R41-CA132256-01).

Title: Endoscopically Guided OCT Imaging for Early Cancer Screening

Amount: 87,933 (total)

Duration: May, 2008 – December, 2009

Role: Principal Investigator of NU Sub-contract (PI: Dr. Nick Iftemia, Physical Sciences, Inc., Andover, MA)

Source: BioCure, Inc., Norcross, GA. Sub-contract funding from the National Cancer Institute Phase I SBIR contract.

Title: Targeted Multifunctional Polymersomes for Cancer Therapy

Amount: \$66,958 (total)

Duration: September, 2009 – June, 2010

Role: Principal Investigator

Source: Physical Sciences, Inc., Andover, MA. Sub-Contract of the National Cancer Institute STTR Phase I Application in response to RFA “*Image Guided Cancer Interventions*” (STTR R41/R42) (1R41-CA135911-01).

Title: Enhanced Contrast Optical Imaging for Screening of Early Stage Pancreatic Cancer

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Amount: \$115,071 (total)

Duration: August, 2008 – July, 2010

Role: Principal Investigator of NU Sub-contract (PI: Dr. Nick Iftemia, Physical Sciences, Inc., Andover, MA)

Source: National Cancer Institute/National Science Foundation, Interdisciplinary Graduate Education and Training (IGERT) Grant (DGE-0504331)

Title: IGERT-Nanomedical Science and Technology

Amount: \$3,320,168 (total)

Duration: October, 2005 – September, 2010

Role: Co-Investigator (PI: Prof. Srinivas Sridhar, The Nanomedicine Education and Research Consortium (NERC), Northeastern University)

Source: National Cancer Institute of the National Institutes of Health. R01 proposal in response to NCI's Alliance for Nanotechnology in Cancer RFA "*Cancer Nanotechnology Platform Partnership Grant*" program (1R01-CA119617-01)

Title: Nanotherapeutic Strategy for Multidrug Resistant Tumors

Amount: \$1,329,399 (total)

Duration: October, 2005 – July, 2011 (with no-cost extension)

Role: Principle Investigator

Source: National Cancer Institute of the National Institutes of Health. ARRA Administrative Supplement for "*Cancer Nanotechnology Platform Partnership Grant*" (1R01-CA119617-S1)

Title: Nanotherapeutic Strategy for Multidrug Resistant Tumors

Amount: \$200,000 (total)

Duration: August, 2009 – July, 2011 (with no-cost extension)

Role: Principle Investigator

Source: Forsyth Institute, Boston, MA. Sub-Contract of the National Institute of Dental and Craniofacial Research's R21 Proposal in Response to Program Announcement PA-03-107 "*NIH Exploratory/Developmental Research Grant Program*" (1R21-DE018782-01A2).

Title: Nanoparticle-Based Antimicrobial Photochemotherapy in Biofilms

Amount: \$140,092 (Sub-contract total)

Duration: August, 2009 – July, 2011

Role: Principal Investigator on NU Subcontract (PI: Dr. Nikos Soukos, Forsyth Institute, Boston, MA)

Source: Medix Corporation, Mexico City, Mexico

Title: Stomach-Specific Non-Antibiotic *H. pylori* Therapy

Amount: \$399,759 (total)

Duration: October, 2008 – May, 2012 (with NCE)

Role: Principal Investigator

Source: Nemucore Medical Innovations, Inc., Sub-Contract of NCI Phase 1 SBIR grant.

Title: EGFR-Targeted Nanoemulsions for Imaging and Therapy of Ovarian Cancer

Amount: \$ 79,310

Duration: September, 2010 – August, 2012

Role: Principle Investigator on NU Sub-Contract

Page

Source: National Cancer Institute of the National Institutes of Health, R21 Proposal in response to RFA PAR-07-034 *"Nanoscience and Nanotechnology in Biology and Medicine"*. (1R21-CA135594)

Title: Nano-Delivery of Mitochondria-Targeted Ceramide to Overcome Tumor Drug Resistance

Amount: \$355,232 (total)

Duration: January, 2010 – December, 2012 (with NCE)

Role: Principal Investigator

Source: National Institute of Diabetes, and Digestive Diseases, and Kidney Diseases (NIDDK) of the National Institutes of Health. R01 proposal in response to RFA *"Nanoscience and Nanotechnology in Biology and Medicine"* program (1R01-DK080477).

Title: Oral Gene Therapy with NiMOS for Inflammatory Bowel Disease

Amount: \$1,334,500 (total)

Duration: March, 2008 – February, 2013 (with NCE)

Role: Principle Investigator

Source: National Institute of Neurological Disorders and Stroke of the National Institutes of Health, R21 Proposal in response to RFA PAR-08-232 *"NINDS Exploratory/Developmental Projects in Translational Research (R21)"*. (1R21-NS066984)

Title: Multifunctional Nanoemulsions for Modulation of BBB Transport

Amount: \$429,000 (total)

Duration: February, 2010 – April, 2013 (with NCE)

Role: Principal Investigator

Source: Northeastern University-Dana Farber Cancer Institute Joint Research Program Cancer Drug Development

Title: Evaluating Synergy between Inhibition of Replication and Promotion of Apoptosis in the Treatment of Ovarian Cancer

Amount: \$100,000 (total)

Duration: July 1, 2012 – June 31, 2014

Role: Principal Investigator (in Collaboration with Dr. Michael Goldberg, Dana-Farber Cancer Institute)

Source: Merrimack Pharmaceuticals, Inc., Cambridge, MA

Title: *In Vivo* Imaging Study

Amount: \$35,000 (total)

Duration: August 1, 2014 – June, 2015

Role: Principal Investigator

Source: Novartis Vaccine and Diagnostics, Cambridge, MA

Title: Pharm Sci Industrial Graduate Fellowship Program (designated to Ms. Ruchi Shah)

Amount: \$159,300 (total)

Duration: May, 2012 – August, 2015

Role: Principal Investigator

Source: Northeastern University Tier-1 Grant

Title: A Cyber-Physical Platform for Rapid Development of Nano-Delivery Systems

Amount: \$50,000 (total)

Duration: July 1, 2014 – December, 2015

Role: Principal Investigator (in Collaboration with Dr. Ravi Sundaram, College of Computer and Information Science, Northeastern University)

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Source: National Cancer Institute of the National Institutes of Health proposal in response to NCI's Alliance for Nanotechnology in Cancer RFA CA-09-012 "*Center of Cancer Nanotechnology Excellence (CCNE) U54 Grant*" program (1U54-CA151881. Project #3).

Title: Multi-Modal Therapy for Pancreatic Cancer with Targeted Nanovectors

Amount: \$1,420,972 (total project funding); \$13.9 million (total CCNE funding)

Duration: September, 2010 – December 2015 (with NCE)

Role: Principle Investigator of Project #3 (CCNE PI: Prof. Vladimir Torchilin, Department of Pharmaceutical Sciences, Northeastern University)

Source: National Cancer Institute of the National Institutes of Health proposal in response to the NCI's Alliance for Nanotechnology in Cancer RFA CA-09-013 "*Cancer Nanotechnology Platform Partnership U01 Grant*" program (1U01-CA151452)

Title: Combinatorial-Designed Nano-Platforms to Overcome Tumor Drug Resistance

Amount: \$2,317,537 (total)

Duration: September, 2010 – August, 2016 (with NCE)

Role: Principle Investigator

Source: National Science Foundation, Interdisciplinary Graduate Education and Training (IGERT) Grant (DGE-0965843)

Title: IGERT-Nanomedical Science and Technology

Amount: \$3,178,512 (total)

Duration: September, 2010 – August, 2016 (with NCE)

Role: Co-Principal Investigator (PI: Prof. Srinivas Sridhar, The Nanomedicine Education and Research Consortium (NERC), Northeastern University)

Source: Nemucore Medical Innovations, Inc., Wellesley, MA. Sub-Contract of NCI proposal in response to Request for Application "*Academic-Industrial Partnerships for Translation of In Vivo Imaging Systems for Cancer Investigations (R01)*" PAR-10-169 (1R01-CA158881)

Title: Integrated Image-Guided Targeted Therapy for Refractory Ovarian Cancer

Amount: \$3,138,368 (total), NU share: \$823,893

Duration: April, 2011 – December 2016 (with NCE)

Role: Principal Investigator

Source: Northeastern University-Houston Methodist Research Institute Collaboration Grant

Title: Non-Viral Telomerase Gene Therapy in Progeria

Amount: \$75,000 (total)

Duration: August 1, 2015 – July 31, 2016

Role: Principal Investigator (in Collaboration with Dr. John P. Cooke, Houston Methodist Research Institute, Houston, TX)

Source: Moderna Therapeutics, Inc. Cambridge, MA

Title: Oral mRNA Delivery and Transfection with Multicompartmental Systems

Amount: \$93,543 (total)

Duration: July 1, 2016 – April 30, 2017

Role: Principal Investigator

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Source: National Cancer Institute of the National Institutes of Health, R21 Proposal in response to PAR13-146 "NCI Exploratory/Developmental Research Grant Program (NCI Omnibus R21)". (R21 proposal CA-179652-A1).

Title: Targeted Platinates/siRNA Combination Therapy for Resistant Lung Cancer

Amount: \$427,625 (total)

Duration: April 1, 2014 – March 31, 2017 (with NCE)

Role: Principal Investigator

Source: National Institute of General Medical Sciences, National Institutes of Health R01 grant in response to RFA "PAR-10-142 Interface of the Life and Physical Sciences" (1R01-GM098117)

Title: Impact of Lipids on Compound Absorption: Mechanistic Studies and Modeling

Amount: \$2,315,953 (total); Co-PI Share: \$238,330

Duration: July, 2012 – June, 2017

Role: Co-Investigator (PI: Rebecca Carrier, Department of Chemical Engineering, Northeastern University)

Source: Northeastern University Tier-1 Grant

Title: Engineering a Sprayable Multifunctional Wound Dressing

Amount: \$50,000 (total)

Duration: July 1, 2016 – December 30, 2017

Role: Principal Investigator (in Collaboration with Dr. Nasim Annabi, Department of Chemical Engineering in the College of Engineering at Northeastern University)

Source: National Institute of Diabetes, and Digestive Diseases, and Kidney Diseases (NIDDK) of the National Institutes of Health. (1 R01 DK098655)

Title: Hepatic Insulin Resistance and Metabolic Disease

Amount: \$2,427,993 (total), NU share: \$212,447

Duration: April 1, 2013 – March 31, 2018

Role: PI of NU Sub-Contract (PI: Morris F. White, Children's Hospital/Harvard Medical School, Boston, MA)

Source: National Cancer Institute of the National Institutes of Health, R56 "Bridge" Grant on the NCI Nanotechnology for Cancer IRCN (U01) Submission

Title: Integrated Nano-Therapeutics to Overcome Tumor Plasticity and Resistance

Amount: \$300,000 (total)

Duration: September, 2017 – August, 2018

Role: Principal Investigator

Source: Targagenix, Inc., Stony Brook, NY - Sub-Contract of NCI SBIR Contract

Title: Nanoemulsion Formulation and IND Enabling Studies of a Novel Cancer Stem Cell Cytotoxic Agent

Amount: \$330,000 (total)

Duration: November, 2015 – October, 2018

Role: Principal Investigator

Source: Takeda Vaccines, Cambridge, MA

Title: Determination of Stability of Inactivated Zika Viral Vaccine Formulation

Amount: \$79,751 (total)

Duration: February, 2018 – October, 2018

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Role: Principal Investigator

Source: National Institute of Biomedical Imaging and Bioengineering of the National Institutes of Health, R21 Proposal in response to PA-16-040 "Exploratory/Developmental Bioengineering Research Grants (EBRG) [R21]". (R21 proposal EB-023025-01).

Title: Oral Gene Delivery to Improve Iron Overload Disorders

Amount: \$419,425 (total)

Duration: June, 2016 – March, 2019 (with NCE)

Role: Co-Principal Investigator (In Collaboration with Dr. Jonghan Kim, Department of Pharmaceutical Sciences, School of Pharmacy at Northeastern University)

Source: Northeastern University-Dana Farber Cancer Institute Joint Research Program on Cancer Drug Development

Title: MicroRNA-Based Reprogramming of Tumor-Associated Macrophages in Ovarian Cancer

Amount: \$100,000 (total)

Duration: August, 2017 – July, 2019

Role: Principal Investigator (in Collaboration with Dr. Michael Goldberg, Dana-Farber Cancer Institute)

PATENTS AND INVENTION DISCLOSURES

Amiji, M.M. *"Biocompatible Articles and Method of Making Same"*. United States Patent Number 5,885,609. Issued: March 1999.

Amiji, M.M. *"Drug Delivery Using pH-Sensitive Semi-Interpenetrating Network Hydrogels"*. United States Patent Number 5,904,927. Issued: May 1999.

Langer, R.S., Lynn, D.M., Putnam, D., **Amiji, M.M.**, and Anderson, D.G. *"Biodegradable Poly(Beta-Amino Esters) and Uses Thereof"*. United States Patent Number 6,998,115. Issued: February, 2006.

Langer, R.S., Lynn, D.M., Putnam, D., **Amiji, M.M.**, and Anderson, D.G. *"Biodegradable Poly(Beta-Amino Esters) and Uses Thereof"*. European Patent Application. (Serial number 019775410-2115-US0131270, Filed: October, 2001).

Amiji, M.M. and Taqieddin, E.S. *"Hybrid Immobilized Catalytic System with Controlled Permeability"* United States Patent Application US2004/0266026, Pending (Filed: January, 2003).

Amiji, M.M., Shenoy, D.B., and van Vlerken, L.E. *"Nanoparticulate Delivery Systems for Treating Multi-drug Resistance"*. United States Patent Application, US2006/0257493, Pending (Filed: April, 2006).

Amiji, M.M. and Tiwari, S.K. *"Novel Nanoemulsion Formulations"* United States Patent Application US2007/0148194, Pending (Filed: November, 2006).

Hirt, T., Lu, Z., Meir, W., and **Amiji, M.** *"Mucoadhesive Vesicles for Drug Delivery"*. PCT and United States Patent Application PCT/US2008/12/157,144. Pending (Filed: August, 2008).

Hanson, R., **Amiji, M.**, and Weissig, V. *"Precision-Guided Nanoparticle System for Drug Delivery"* PCT and United States Patent Application PCT/US2008/01766, Pending (Filed: February, 2008).

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Amiji, M. and Iyer, A.K. “*Multi-Functional Self-Assembling Polymeric Nanosystems*”. PCT and United States Patent Application US200961/246,355 and WO 2010042823-A1 Pending (Filed: September, 2009).

Amiji, M., Kalariya, M., Jain, S., and Attarwala, A. “*Multi-Compartmental Macrophage Delivery*”. PCT and United States Patent Application US 20130243689-A1 and WO 2011119881-A1, Pending (Filed: March, 2011).

Amiji, M., Ganta, S., and Tsai, P.-C. “*Multimodal Diagnostic Technology for Early Stage Cancer Lesions*”. PCT and United States Patent Application US 20130224120-A1 and WO 2011119822-A1, Pending (Filed March, 2011).

Amiji, M. and Iyer, A.K. “*Biodegradable Polymeric Buffers*”. PCT and United States Patent Application WO 2014008283-A3, Pending (Filed: July, 2013).

Amiji, M. and Singh, A. “*Releasable Magnetic Cell Capture Technology*”. PCT and United States Patent Application WO 2014110578-A1, Pending (Filed: January, 2014).

Amiji, M., Trivedi, M., and Singh, A. “*Mitochondrial Reprogramming by Non-Viral Nucleic Acid Delivery*”. Provisional United States Patent Application (Filed: September, 2014).

Amiji, M., Singh, A., Nascimento, A.V., and Su, M.J. “*Cellular Reprogramming by Modulation of Extracellular Vesicle (Exosome) Composition*”. Provisional United States Patent Application (Filed: September, 2014).

PRESENTATIONS

American Association of Pharmaceutical Scientists Annual Meeting, Orlando, FL. Poster presentation entitled “*Adsorption Isotherms of Doxorubicin on Oxidized Dextran*”. November, 1988.

Controlled Release Society Annual Meeting, San Francisco, CA. Podium presentation entitled “*Mucoadhesive Hydrogels Effective at Neutral pH*”. March, 1989.

Society for Biomaterials Annual Meeting, Santa Fe, NM. Podium presentation entitled “*The Minimum Amount of Biologically Active Fibrinogen Necessary for Surface-Induced Platelet Activation*”. April, 1989.

NIH Conference on Cardiovascular Science and Technology, Bethesda, MD. Podium presentation entitled “*Mechanism of Surface Passivation by Albumin*”. May 1990.

Surfaces in Biomaterials Foundation First Annual Meeting, Minneapolis, MN. Podium presentation entitled “*Mechanism Study on the Prevention of Surface-Induced Platelet Activation by Adsorbed Albumin*”. March, 1991.

Society for Biomaterials Annual Meeting, Scottsdale, AZ. Podium presentation entitled “*Prevention of Protein Adsorption and Platelet Adhesion by Steric Repulsion*”. May, 1991.

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American Chemical Society National Meeting, Washington, DC. Podium presentation entitled "*Surface Passivating Effect of PEO/PPO/PEO Triblock Copolymers*". August, 1992.

American Chemical Society National Meeting, Washington, DC. Podium presentation entitled "*Analysis on the Surface Adsorption of PEO/PPO/PEO Triblock Copolymers*". August, 1992.

American Association of Pharmaceutical Scientists Annual Meeting, San Antonio, TX. Podium presentation entitled "*Prevention of Protein Adsorption on Surfaces by PEO/PPO/PEO Triblock Copolymers*". November, 1992.

Society for Biomaterials Annual Meeting, Boston, MA. "*Adsorption Behavior of PEO/PPO/PEO Triblock Copolymers on DDS-Glass*". April, 1994.

Society for Biomaterials Annual Meeting, Boston, MA. Podium presentation entitled "*Development of Poly(ethylene oxide)-Chitosan Blend Membranes for Hemodialysis*". April, 1994.

American Chemical Society Annual Meeting, Washington, DC, Podium presentation entitled "*Chitosan-Poly(ethylene oxide) Semi-IPN as a pH-Sensitive Drug Delivery System*". August, 1994.

American Association of Pharmaceutical Scientists Annual Meeting, Orlando, FL. Podium presentation entitled "*Pyrene Fluorescence Study of Insulin Denaturation and Aggregation at Hydrophobic Interfaces*". November, 1994.

Controlled Release Society Annual Meeting, Seattle, WA. Poster presentation entitled "*Chitosan-Poly(Ethylene Oxide) Hydrogels for pH-Sensitive Oral Drug Delivery*". August, 1995.

American Chemical Society's Conference on Formulations and Drug Delivery, Boston, MA. Podium presentation entitled "*Site-specific Oral Delivery of Antibiotics using pH-Sensitive Hydrogels*". October, 1995.

American Association of Pharmaceutical Scientists, Eastern Regional Meeting, New Brunswick, NJ. Poster presentation entitled "*Site-Specific Delivery of Antibiotics for the Treatment of Helicobacter pylori Infection in Peptic Ulcer Disease*". June, 1995.

Fifth World Biomaterials Congress, Toronto, Ontario, Canada. Podium presentation entitled "*Surface Modification of Chitosan Hemodialysis Membranes with Anionic Polysaccharides*". June, 1996.

Surfaces in Biomaterials '96 Symposium, Chandler, AZ. Poster presentation entitled "*Modification of Chitosan Membrane Surfaces by Complexation-Interpenetration of Anionic Polysaccharides*" September, 1996.

Nineteenth Annual Undergraduate Research Seminar, Morgantown, WV. Poster presentation entitled "*Factors Influencing Stomach-Specific Antibiotic Delivery for H. pylori Infection*". October, 1997.

First International Symposium on Advanced Biomaterials, Montréal, Quebec, Canada. Podium presentation entitled "*Chitosan Surface Modification with Anionic Poly(Ethylene Glycol) Derivative for Improved Blood Compatibility*." October, 1997.

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American Association of Pharmaceutical Scientists Annual Meeting, Boston, MA. Poster presentation entitled "*The Role of Gastric pH and Mucin Permeability on Localized Antibiotic Delivery for H. pylori Infection*". November, 1997.

American Association of Pharmaceutical Scientists Annual Meeting, Boston, MA. Poster presentation entitled "*Mucoadhesive Chitosan Microspheres for Stomach-Specific Antibiotic Delivery*". November, 1997.

American Association of Pharmaceutical Scientists Annual Meeting, Boston, MA. Poster presentation entitled "*Surface Modification of Chitosan by Polyelectrolyte Complexation-Interpenetration to Improve Biocompatibility*". November, 1997.

Society for Biomaterials Annual Meeting, Providence, RI. Podium presentation entitled "*Novel Thermogelling Paclitaxel Formulation for Localized Delivery*". May, 1999.

Society for Biomaterials Annual Meeting, Providence, RI. Podium presentation entitled "*Surface Modification of Chitosan Microspheres to Improve Biocompatibility*". May, 1999.

Controlled Release Society Annual Meeting, Boston, MA. Poster presentation entitled "*Membranes Formed by Physical Interpenetration of Chitosan with PEO/PPO/PEO Triblock Copolymers*". June, 1999.

American Association of Pharmaceutical Sciences Annual Meeting. Indianapolis, IN. Poster presentation entitled "*Preparation and Characterization of Cross-linked Chitosan Microspheres for Delivery of Tetracycline Locally in the Stomach*". November, 2000.

American Association of Pharmaceutical Sciences, Pharmaceutical Congress of the Americas, Orlando, FL. Poster presentation entitled "*Intratumoral Administration of Paclitaxel in a Thermogelling Pluronic® F-127 Formulation*". March, 2001.

American Association of Pharmaceutical Sciences, Pharmaceutical Congress of the Americas, Orlando, FL. Poster presentation entitled "*Biodegradable Chitin-Paclitaxel Microparticle Formulations for Localized Drug Delivery*". March, 2001.

American Association of Pharmaceutical Scientists, Pharmaceutical Congress of the Americas, Orlando, FL. Poster presentation entitled "*Permselective Membranes Prepared by Physical Interpenetration of Chitosan with PEO/PPO/PEO Triblock Copolymers*". March, 2001.

American Association of Pharmaceutical Scientists, Northeast Regional Discussion Group Annual Meeting, Rocky Hill, CT. Poster presentation entitled "*Poly(epsilon-caprolactone) Nanoparticles for Intracellular Delivery of Tamoxifen*". April, 2001.

American Association of Pharmaceutical Scientists, Northeast Regional Discussion Group Annual Meeting, Rocky Hill, CT. Poster presentation entitled "*Poly(ethylene glycol)-Modified Gelatin Nanoparticles as Long-Circulating Intracellular Delivery Vehicle*". April, 2001.

American Association of Pharmaceutical Scientists Annual Meeting, Denver, CO. Poster presentation entitled "*Poly(epsilon-caprolactone) Nanoparticles for Intracellular Delivery of Tamoxifen*". October, 2001.

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American Association of Pharmaceutical Scientists Annual Meeting, Denver, CO. Poster presentation entitled "*Perm-Selective Alginate-Chitosan Hybrid Microcapsules for Enzyme Immobilization*". October, 2001.

American Association of Pharmaceutical Scientists, Northeast Regional Discussion Group Annual Meeting, Rocky Hill, CT. Poster presentation entitled "*Long-Circulating, pH-Sensitive Poly(beta-amino ester) Nanoparticles for Tumor-Selective Paclitaxel Delivery*". April, 2002.

American Association of Pharmaceutical Scientists Annual Meeting, Toronto, Ontario, Canada. Poster presentation entitled "*Cellular Uptake, Trafficking, and DNA Transfection Studies with Poly(ethylene glycol)-Modified Gelatin Nanoparticles*". November, 2002.

American Association of Pharmaceutical Scientists, Northeast Regional Discussion Group Annual Meeting, Rocky Hill, CT. Poster presentation entitled "*In Vitro Evaluation of DNA Delivery to Tumor Cells Using Poly(ethylene glycol)-Modified Gelatin Nanoparticles*". April, 2003.

American Association of Pharmaceutical Scientists, Northeast Regional Discussion Group Annual Meeting, Rocky Hill, CT. Poster presentation entitled "*Effect of Chemical Cross-linking of Chitosan Microspheres on Gastric Residence and Local Tetracycline Concentrations in Fasted Gerbils for Local Treatment of H. pylori Infection*". April, 2003.

American Association of Pharmaceutical Scientists, Northeast Regional Discussion Group Annual Meeting, Rocky Hill, CT. Poster presentation entitled "*Chitosan Stabilized Colloidal Gold Complexes: Cationic Probes for Intracellular DNA Trafficking and Delivery*". April, 2003.

American Association of Pharmaceutical Scientists, Northeast Regional Discussion Group Annual Meeting, Rocky Hill, CT. Poster presentation entitled "*Plasmid DNA Encapsulation in a Hybrid Nanoparticles-in-Microsphere System for Oral Delivery*". April, 2004.

American Association of Pharmaceutical Scientists, Northeast Regional Discussion Group Annual Meeting, Rocky Hill, CT. Poster presentation entitled "*Preparation of Thiolated Gelatin Nanoparticles for Rapid Intracellular Delivery in Response to Glutathione*". April, 2004.

American Association of Pharmaceutical Scientists, Northeast Regional Discussion Group Annual Meeting, Rocky Hill, CT. Poster presentation entitled "*Polymeric Nanoparticles for Targeted and Controlled Tamoxifen Delivery in Breast Cancer: In Vitro and In Vivo Investigations*". April, 2004.

American Association of Pharmaceutical Scientists, Northeast Regional Discussion Group Annual Meeting, Rocky Hill, CT. Poster presentation entitled "*Biodistribution and Targeting Potential of Poly(ethylene glycol)-Modified Gelatin Nanoparticles in Tumor-Bearing Mice*". April, 2004.

American Association of Pharmaceutical Scientists Annual Meeting, Baltimore, MD. Poster presentation entitled "*Polymeric Nanoparticles for Targeted and Controlled Tamoxifen Delivery in Breast Cancer: In-vitro and In-vivo Investigations*". November, 2004.

American Association of Pharmaceutical Scientists Annual Meeting, Baltimore, MD. Poster presentation entitled "*Preparation of Thiolated Gelatin Nanoparticles for Rapid Intracellular Delivery in Response to Glutathione*". November, 2004.

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American Association of Pharmaceutical Scientists Annual Meeting, Baltimore, MD. Poster presentation entitled *"Biodistribution and Targeting Potential of Poly(ethylene glycol)-Modified Gelatin Nanoparticles in Tumor-Bearing Mice"*. November, 2004.

American Association of Pharmaceutical Scientists Annual Meeting, Baltimore, MD. Poster presentation entitled *"Nanoparticles-in-Microsphere Hybrid Systems for Oral DNA Vaccine Delivery"*. November, 2004.

Materials Research Society Fall National Meeting, Boston, MA. *"Biomedical Applications of Gold Nanoparticles Functionalized Using Hetero-Bifunctional Poly(ethylene glycol) Spacer"*. December, 2004.

Materials Research Society Fall National Meeting, Boston, MA. *"Biodegradable Polymeric Nanoparticles for Tumor-Selective Tamoxifen Delivery: In Vitro and In Vivo Studies"*. December, 2004.

Materials Research Society Fall National Meeting, Boston, MA. *"Biodistribution and Tumor-Targeting Potential of Poly(ethylene glycol)-Modified Gelatin Nanoparticles"*. December, 2004.

American Association of Pharmaceutical Scientists, Northeast Regional Discussion Group Annual Meeting, Rocky Hill, CT. Poster presentation entitled *"Polymeric Nanoparticles for Targeted and Controlled Tamoxifen Delivery in Breast Cancer: In-Vitro and In-Vivo Investigations"*. April, 2005.

American Association of Pharmaceutical Scientists, Northeast Regional Discussion Group Annual Meeting, Rocky Hill, CT. Poster presentation entitled *"Plasmid DNA Encapsulation in a Hybrid Nanoparticles-in-Microsphere System for Oral Delivery"*. April, 2005.

American Association of Pharmaceutical Scientists, Northeast Regional Discussion Group Annual Meeting, Rocky Hill, CT. Poster presentation entitled *"Improved Oral Delivery of Hydrophobic Drugs with Novel Nanoemulsion Formulations"* April, 2005.

Nano Science and Technology Institute's Nano2005 Conference and Trade Show, Anaheim, CA. *"Biomedical Applications of Gold Nanoparticles Functionalized Using Hetero-bifunctional Poly(ethylene glycol) Spacer"*. May, 2005.

Nano Science and Technology Institute's Nano2005 Conference and Trade Show, Anaheim, CA. *"Super-paramagnetic Iron Oxide-Gold Core-Shell Nanoparticles for Biomedical Applications"*. May, 2005.

American Association of Pharmaceutical Scientists Annual Meeting, Nashville, TN. Poster presentation entitled *"Formulation Optimization for the Nanoparticles-In-Microsphere Hybrid Oral Delivery System Using Factorial Design"*. November, 2005.

American Association of Pharmaceutical Scientists Annual Meeting, Nashville, TN. Poster presentation entitled *"Formulation Development and In Vivo Biodistribution Studies of Poly(ethylene glycol)-Modified Thiolated Gelatin Nanoparticles"*. November, 2005.

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American Association of Pharmaceutical Scientists Annual Meeting, Nashville, TN. Poster presentation entitled "*Novel Nanoemulsions for Improved Oral Delivery of Hydrophobic Drugs*". November, 2005.

American Association of Pharmaceutical Scientists Annual Meeting, Nashville, TN. Poster presentation entitled "*Nanoemulsion Formulations for Improved CNS Drug Delivery*". November, 2005.

American Association of Pharmaceutical Scientists Annual Meeting, Nashville, TN. Poster presentation entitled "*Application of Statistical Factorial Design for the Preparation of Poly(styrene-*b*-isobutylene-*b*-styrene) Triblock Copolymer Microspheres*". November, 2005

American Association of Pharmaceutical Scientists, Northeast Regional Discussion Group Annual Meeting, Rocky Hill, CT. Poster presentation entitled "*Intracellular Delivery of Saquinavir in Biodegradable Polymeric Nanoparticles for HIV/AIDS*" April, 2006.

American Association of Pharmaceutical Scientists, Northeast Regional Discussion Group Annual Meeting, Rocky Hill, CT. Poster presentation entitled "*Improved Oral Delivery of Saquinavir in Nanoemulsion Formulations for HIV/AIDS*". April, 2006.

American Association of Pharmaceutical Scientists, Northeast Regional Discussion Group Annual Meeting, Rocky Hill, CT. Poster presentation entitled "*Development, Characterization and Transfection of the Plasmid DNA Encapsulated in Nanoparticles-in-Microsphere Formulations for Oral Delivery*". April, 2006.

American Association of Pharmaceutical Scientists, Northeast Regional Discussion Group Annual Meeting, Rocky Hill, CT. Poster presentation entitled "*Tumor-Targeted Delivery of Hydrophobic Drugs in pH-Sensitive Poly(ethylene oxide)-Modified Poly(beta-amino ester) Nanoparticles*". April, 2006.

Society for Biomaterials Annual Meeting, Pittsburgh, PA. Podium presentation entitled "*Modulation of Intracellular Ceramide Using Polymeric Nanoparticles to Overcome Multidrug Resistance in Tumor Cells*". April, 2006.

Society for Biomaterials Annual Meeting, Pittsburgh, PA. Poster presentation entitled "*Development of the Nanoparticles-in-Microsphere Hybrid Formulations for Oral Delivery of Plasmid DNA*". April, 2006.

Society for Biomaterials Annual Meeting, Pittsburgh, PA. Poster presentation entitled "*Novel Nanoemulsions for Improved Oral Delivery of Hydrophobic Drugs*". April, 2006.

Nano Science and Technology Institute's Nano2006 Conference and Trade Show, Boston, MA. Podium presentation entitled "*Modulation of Intracellular Ceramide Using Polymeric Nanoparticles to Overcome Multidrug Resistance in Tumor Cells*". May, 2006.

Nano Science and Technology Institute's Nano2006 Conference and Trade Show, Boston, MA. Poster presentation entitled "*Formulation Optimization for the Nanoparticles-in-Microsphere Hybrid Oral Delivery Systems Using Factorial Design*". May, 2006.

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Nano Science and Technology Institute's Nano2006 Conference and Trade Show, Boston, MA. Poster presentation entitled "*Novel Nanoemulsions for Improved Oral Delivery of Poorly Soluble Drugs*". May, 2006.

Nano Science and Technology Institute's Nano2006 Conference and Trade Show, Boston, MA. Poster presentation entitled "*Characterization and In Vivo Biodistribution Studies with Poly(ethylene glycol)-Modified Thiolated Gelatin Nanoparticles*". May, 2006.

Controlled Release Society Annual Meeting, Vienna, Austria. Poster presentation entitled "*Poly(Styrene-*b*-Isobutylene-*b*-Styrene) Triblock Copolymer Microspheres for Sustained Release Drug Delivery*". July, 2006.

Society of Neuroscience 2006 Annual Meeting, Atlanta, GA. Poster presentation entitled "*Brain Delivery of Proteins by the Intranasal Route of Administration Using Cationic Liposomes*". October, 2006

The First National Cancer Institute's Alliance in Nanotechnology Principal Investigator Meeting. San Diego, CA. Poster presentation entitled "*Multifunctional Nanosystems to Overcome Drug Resistance in Cancer*". October, 2006.

The First National Cancer Institute's Alliance in Nanotechnology Principal Investigator Meeting. San Diego, CA. Poster presentation entitled "*Modulation of Multidrug Resistance in Cancer with Polymer Blend Nanoparticles*". October, 2006.

American Association of Pharmaceutical Scientists Annual Meeting, San Antonio, TX. Poster presentation entitled "*Tumor-Targeted Delivery of Hydrophobic Drugs in pH-Sensitive Poly(ethylene oxide)-Modified Poly(beta-amino ester) Nanoparticles*". November, 2006.

American Association of Pharmaceutical Scientists Annual Meeting, San Antonio, TX. Poster presentation entitled "*Development and Characterization of Nanoemulsion Formulations Containing Multimodal Therapeutics for Brain Tumor*". November, 2006.

American Association of Pharmaceutical Scientists Annual Meeting, San Antonio, TX. Poster presentation entitled "*Biodegradable Polymeric Nanoparticles for Intracellular Saquinavir Delivery in HIV/AIDS*". November, 2006.

American Association of Pharmaceutical Scientists Annual Meeting, San Antonio, TX. Poster presentation entitled "*Oral Plasmid DNA Administration and Transfection Using Nanoparticles-in-Microsphere Formulations*". November, 2006.

American Association of Pharmaceutical Scientists Annual Meeting, San Antonio, TX. Poster presentation entitled "*Modulation of Multidrug Resistance in Cancer with Polymer Blend Nanoparticles*". November, 2006.

American Association of Pharmaceutical Scientists Annual Meeting, San Antonio, TX. Poster presentation entitled "*Tumor-Targeted sFlt-1 Gene Delivery Using Long-Circulating Thiolated Gelatin Nanoparticles*". November, 2006.

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American Association of Pharmaceutical Scientists Annual Meeting, San Antonio, TX. Poster presentation entitled *"Improved Oral Delivery of Saquinavir in Nanoemulsion Formulations for HIV/AIDS"*. November, 2006.

Controlled Release Society Annual Meeting, Long Beach, CA. Poster presentation entitled *"Gastrointestinal Gene Delivery in Mice using Polymeric Nanoparticles-in-Microsphere Oral System"*. July, 2007.

Controlled Release Society Annual Meeting, Long Beach, CA. Poster presentation entitled *"Design and Development of a Polymer-Blend Nanoparticle Drug Delivery System to Overcome Multidrug Resistance in Cancer"*. July, 2007.

Controlled Release Society Annual Meeting, Long Beach, CA. Poster presentation entitled *"Paclitaxel and Ceramide Combination Therapy in Biodegradable Polymeric Nanoparticles to Overcome Multidrug Resistance in Cancer"*. July, 2007.

The Second National Cancer Institute's Alliance in Nanotechnology Principal Investigator Meeting. Chapel Hill, NC. Poster presentation entitled *"Nanoparticulate Therapeutic Strategy for Intracellular Ceramide Modulation to Lower Apoptotic Threshold and Overcome Multidrug Resistance in Cancer"*. October, 2007.

American Association of Pharmaceutical Scientists Annual Meeting, San Diego, CA. Poster presentation entitled *"Modulation of Intracellular Ceramide Metabolism with Biodegradable Polymeric Nanoparticle-Encapsulated Tamoxifen to Overcome Multidrug Resistance in Cancer."* November, 2007.

American Association of Pharmaceutical Scientists Annual Meeting, San Diego, CA. Poster presentation entitled *"Multifunctional Polymer Blend Nanoparticles for Temporal-Controlled Release of Combination Therapeutics to Overcome Multidrug Resistance of Cancer"*. November, 2007.

American Association of Pharmaceutical Scientists Annual Meeting, San Diego, CA. Poster presentation entitled *"Development of Novel Biodegradable Polymeric Nanoparticles-in-Microsphere Formulation for Local Plasmid DNA Delivery in the Gastrointestinal Tract"*. November, 2007.

American Association of Pharmaceutical Scientists Annual Meeting, San Diego, CA. Poster presentation entitled *"HER2/neu Receptor-Targeted Engineered Gelatin Nanovectors for Gene Delivery and Transfection in Pancreatic Cancer Cells"*. November, 2007.

American Chemical Society Annual Meeting, New Orleans, LA. Podium presentation entitled *"Gene Delivery and Transfection Studies with Lipopolyplexes in Human Endothelial and Smooth Muscle Cells"*. April, 2008.

Nano Science and Technology Institute's Nano2008 Conference and Trade Show, Boston, MA. Podium presentation entitled *"Gene Delivery and Transfection Studies with Lipopolyplexes in Human Endothelial and Smooth Muscle Cells"*. June, 2008.

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Nano Science and Technology Institute's Nano2008 Conference and Trade Show, Boston, MA. Podium presentation entitled "*Epidermal Growth Factor Receptor-Targeted Engineered Gelatin Nanovectors for Gene Delivery and Transfection in Pancreatic Cancer Cells*". June, 2008.

Nano Science and Technology Institute's Nano2008 Conference and Trade Show, Boston, MA. Poster presentation entitled "*Non-condensing Calcium Alginate Microspheres for Macrophage-Selective Gene Delivery and Transfection*". June, 2008.

Nano Science and Technology Institute's Nano2008 Conference and Trade Show, Boston, MA. Poster presentation entitled "*Multifunctional Nanoparticulate System for Simultaneous EGFR Gene Silencing and Enhancement of Apoptosis in Pancreatic Cancer Cells*". June, 2008.

Controlled Release Society Annual Meeting, New York, NY. Podium presentation entitled "*Gene Delivery and Transfection Studies in Smooth Muscle Cells with Lipopolyplexes Immobilized in Gelatin-Coated Stainless Steel Substrates*." July, 2008.

Controlled Release Society Annual Meeting, New York, NY. Poster presentation entitled "*Cellular Trafficking Studies of Ceramide-Loaded Poly(ethylene Oxide)-Modified Poly(epsilon-caprolactone) Nanoparticles with Raman Spectroscopy*." July, 2008.

American Association of Pharmaceutical Scientists Annual Meeting, Atlanta, GA. Poster presentation entitled "*Epidermal Growth Factor Receptor-Targeted Gelatin-Based Nanoparticles for Reporter and Therapeutic Gene Delivery in Human Pancreatic Cancer Cells*". November, 2008.

The Fourth National Cancer Institute's Alliance in Nanotechnology Principal Investigator Meeting. Manhattan Beach, CA. Poster presentation entitled "*Polymer Blend Nanoparticulate System for Combination Paclitaxe/Lonidamine Co-Therapy in Overcoming Multidrug Resistance in Breast and Ovarian Cancer via Exploitation of the Warburg's Effect*". October, 2009.

The Fourth National Cancer Institute's Alliance in Nanotechnology Principal Investigator Meeting. Manhattan Beach, CA. Poster presentation entitled "*Inhibition of ABCD1 (MDR-1) Expression by siRNA Nanoparticulate Delivery System to Overcome Drug Resistance in Osteosarcoma*". October, 2009.

American Association of Pharmaceutical Scientists Annual Meeting, Los Angeles, CA. Poster presentation entitled "*In Vitro Studies with Estradiol-Loaded Omega-3 Fatty Acid-Containing Oil-in-Water Nanoemulsion Formulations for the Treatment of Coronary Restenosis*". November, 2009.

American Association of Pharmaceutical Scientists Annual Meeting, Los Angeles, CA. Poster presentation entitled "*The Effect of Curcumin in Enhancing Oral Absorption and Anti-Tumor Therapeutic Efficacy of Paclitaxel Administered in Nanoemulsion Formulations*". November, 2009.

American Association of Pharmaceutical Scientists Annual Meeting, Los Angeles, CA. Poster presentation entitled "*TNF- α Gene Silencing Using Nanoparticles-in-Microsphere Oral Delivery System in an Inflammatory Bowel Disease Model*". November, 2009.

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Controlled Release Society Annual Meeting, Portland, OR. Poster presentation entitled *"Tuftsin-Modified Alginate Nanoparticles as a Non-Condensing Macrophage-Targeted Gene Delivery System for Anti-Inflammatory Therapy."* July, 2010.

Controlled Release Society Annual Meeting, Portland, OR. Poster presentation entitled *"Preliminary Evaluations of Combination Ceramide/Estradiol Therapy in Coronary Restenosis with Omega-3 Fatty Acid-Containing Nanoemulsion Formulations"*. July, 2010.

Controlled Release Society Annual Meeting, Portland, OR. Poster presentation entitled *"In Vitro Evaluations of Nanoparticle-in-Emulsion Formulations for Gene Delivery and Transfection in Macrophages"*. July, 2010.

American Association of Pharmaceutical Scientists Annual Meeting, New Orleans, LA. Poster presentation entitled *"Preliminary Evaluations of Combination Ceramide/Estradiol Therapy in Atherosclerosis with Omega-3 Fatty Acid-Containing Nanoemulsion Formulations"*. November, 2010.

American Association of Pharmaceutical Scientists Annual Meeting, New Orleans, LA. Podium and poster presentations entitled *"Tuftsin-Modified Alginate Nanoparticles as a Non-Condensing Macrophage-Targeted Gene Delivery System for Anti-Inflammatory Therapy"*. November, 2010.

American Association of Pharmaceutical Scientists Annual Meeting, New Orleans, LA. Poster presentation entitled *"Advances in siRNA Delivery: Preliminary Work in the Development of an siRNA Nanoemulsion Delivery System"*. November, 2010.

American Association of Pharmaceutical Scientists Annual Meeting, New Orleans, LA. Poster presentation entitled *"Advances in siRNA Delivery: Preliminary Work in the Development of an siRNA Nanoemulsion Delivery System"*. November, 2010.

American Association of Pharmaceutical Scientists Annual Meeting, New Orleans, LA. Poster presentation entitled *"Gene Delivery and Transfection in Human Pancreatic Cancer Cells using Epidermal Growth Factor Receptor-Targeted Gelatin Nanoparticles"*. November, 2010.

American Association of Pharmaceutical Scientists, National Biotechnology Conference. San Francisco, CA. Poster presentation entitled *"Therapeutic Gene Delivery and Transfection in Human Pancreatic Cancer Cells Using Epidermal Growth Factor Receptor-Targeted Gelatin Nanoparticles"*. May, 2011.

Nano Science and Technology Institute's Nano2011 Conference and Trade Show, Boston, MA. Podium presentation entitled *"Label-Free Raman Micro-Spectral Imaging of the Micro-Environment of Panc-1 Spheroids"*. June, 2011.

Nano Science and Technology Institute's Nano2011 Conference and Trade Show, Boston, MA. Podium presentation entitled *"Therapeutic Gene Delivery and Transfection in Human Pancreatic Cancer Cells Using Epidermal Growth Factor Receptor-Targeted Gelatin Nanoparticles"*. June, 2011.

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Controlled Release Society Annual Meeting, National Harbor, MD. Poster presentation entitled "*Label-Free Imaging of Panc-1 Human Pancreatic Tumor Spheroids by Raman Microspectroscopy*". July, 2011.

Controlled Release Society Annual Meeting, National Harbor, MD. Poster presentation entitled "*Therapeutic Gene Delivery and Transfection in Human Pancreatic Cancer Cells Using Epidermal Growth Factor Receptor-Targeted Gelatin Nanoparticles*". July, 2011.

17th International Workshop on Single Molecule Spectroscopy and Ultrasensitive Analysis in the Life Sciences, Berlin, Germany. Poster presentation entitled "*Label-Free and Sub-Micron Imaging of Tumor Micro-Environment In Vitro*". September, 2011.

The Fifth National Cancer Institute's Alliance in Nanotechnology for Cancer Annual Principal Investigators Meeting, Boston, MA. Poster presentation entitled "*Combinatorial Library Approach Using Functionally Variant Hyaluronic Acid-Based Self-Assembling Nanosystems for Tumor-Targeted Drug and Oligonucleotide Delivery*". September, 2011.

The Fifth National Cancer Institute's Alliance in Nanotechnology for Cancer Annual Principal Investigators Meeting, Boston, MA. Poster presentation entitled "*Evaluations of Dextran-Based Nanoparticle-Mediated Drug and siRNA Delivery*". September, 2011.

The Fifth National Cancer Institute's Alliance in Nanotechnology for Cancer Annual Principal Investigators Meeting, Boston, MA. Poster presentation entitled "*Multimodal Therapeutic Approach for Pancreatic Cancer: Delivery of Combination wt-p53 Gene and Gemcitabine in Epidermal Growth Factor Receptor-Targeted Gelatin Nanoparticles*". September, 2011.

Federation of Analytical Chemistry and Spectroscopy Societies (FACSS) 38th Annual Meeting. Reno, NV. Posium presentation entitled "*Label-Free Sub-Micron Imaging of Biological Systems*". October, 2011.

American Association of Pharmaceutical Scientists Annual Meeting, Washington, DC. Poster presentation entitled "*Combinatorial Library Approach Using Functionally Variant Hyaluronic Acid-Based Self-Assembling Nanosystems for Tumor-Targeted Drug and Oligonucleotide Delivery*". October, 2011.

American Association of Pharmaceutical Scientists Annual Meeting, Washington, DC. Poster presentation entitled "*Squalane oil Multiple Emulsion Formulations for Enhanced Immune Response to Peptide-Based Melanoma Vaccine*". October, 2011.

American Association of Pharmaceutical Scientists Annual Meeting, Washington, DC. Poster presentation entitled "*Macrophage-Targeted Tuftsin-Modified Alginate Nanoparticles for Anti-Inflammatory Gene Therapy in the Treatment of Rheumatoid Arthritis*". October, 2011.

American Association of Pharmaceutical Scientists Annual Meeting, Washington, DC. Poster presentation entitled "*Multimodal Therapeutic Approach for Pancreatic Cancer: Delivery of Combination wt-p53 Gene and Gemcitabine in Epidermal Growth Factor Receptor-Targeted Gelatin Nanoparticles*". October, 2011.

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Connective Tissue Oncology Society (CTOS) Annual Meeting, Chicago, IL. Podium presentation entitled "*Dextran-Based Nanoparticulate Delivery System to Overcome Multidrug Resistance in Osteosarcoma*". October, 2011.

Eight Annual Workshop on FT-IR Spectroscopy in Microbiological and Medical Diagnostics. Berlin, Germany. Poster presentation entitled "*Raman-Active Gold Nanoparticles as Beacons in Cervical Cancer Cells*". October, 2011.

International Society of Pharmaceutical Engineers Annual Meeting. Dallas, TX. Podium presentation entitled "*Macrophage-Targeted Tuftsin-Modified Alginate Nanoparticles for Anti-Inflammatory Gene Therapy in the Treatment of Rheumatoid Arthritis*". November, 2011.

American Association of Pharmaceutical Scientists, National Biotechnology Conference. San Diego, CA. Poster presentation entitled "*Macrophage-Targeted Tuftsin-Modified Alginate Nanoparticles for Anti-Inflammatory Gene Therapy in the Treatment of Experimental Arthritis*". May, 2012.

INVITED PRESENTATIONS AND TUTORIALS

Massachusetts College of Pharmacy and Allied Health. Division of Pharmaceutical Sciences. Boston, MA. "*Formulation of Controlled Release Dosage Forms*". May, 1996.

Advanced Magnetics, Inc., Cambridge, MA. "*Poly(Ethylene Glycol)-Modified Biomaterial Surfaces*". January, 1998.

Innovative Imaging Systems, Inc., North Billerica, MA. "*Polymers for Controlled Drug Delivery Systems*". August, 1998.

Kuwait University, Faculty of Pharmacy, Safat, Kuwait. "*Medical and Pharmaceutical Applications of Chitosan*". February, 1999.

Tufts University, Department of Chemical Engineering and Bioengineering and Center for Biotechnology Engineering. Medford, MA. "*Chitosan-Based Biomaterials and Drug Delivery Systems*". March, 2000.

Massachusetts Institute of Technology (MIT), Department of Chemical Engineering, Cambridge, MA. "*Polymeric Site-Specific Drug Delivery Systems*". September, 2000.

Zycos, Inc., Lexington, MA. "*Cationic Interpenetrating Network Hydrogels for DNA Delivery*". December, 2000.

Northeastern University, Department of Pharmaceutical Sciences, Boston, MA. "*Novel Biodegradable pH-Responsive Polymers for Intracellular Delivery*". March, 2001.

Northeastern University, School of Pharmacy, Boston, MA. "*Polymeric Delivery Systems for Drugs and Genes*". March, 2002.

Cambridge Scientific, Inc., Cambridge, MA. "*Polymeric Drug and Gene Delivery Systems*". March, 2002.

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Marine Polymer Technologies, Inc., Topsfield, MA. *"Chitosan-Based Biomaterials and Drug Delivery Systems"*. April, 2002.

Northeastern University, Biotechnology Academic Steering Committee, Boston, MA. *"Polymeric Biomaterials and Drug Delivery Systems"*. January, 2003.

Northeastern University, Department of Biology, Boston, MA. *"Polymeric Biomaterials and Delivery Systems"*. April, 2003.

Northeastern University, Technology Transfer and Biotechnology Symposium, Boston, MA. *"Polymeric Biomaterials and Drug Delivery Systems"*. April, 2003.

Catalyst Oncology, Inc., Providence, RI. *"Tumor-Targeted Polymeric Nanoparticle Delivery Systems"*. December, 2003.

Archemix, Inc., Cambridge, MA. *"Nanotechnology for Drug Delivery"*. May, 2004.

Novartis Institute for Biomedical Research, Cambridge, MA. *"Polymeric Technologies for Delivery of Drugs and Genes"*. August, 2004.

University of MA at Lowell, Lowell, MA. *"Polymer-Based Technologies for Targeted Delivery of Drugs and Genes"*. February, 2005.

Spherics, Inc., Lincoln, RI. *"Polymeric Delivery Systems for Drugs and Genes"*. April, 2005.

Northeastern University, Department of 2005 Pharmaceutical Sciences Research Showcase, Boston, MA. *"Nanotechnology for Tumor-Targeted Delivery of Drugs and Genes"*. May, 2005.

Nano Science and Technology Institute's Nano2005 Conference and Trade Show, Anaheim, CA. *"Nanotechnology for Medical Diagnosis, Imaging, and Therapy – a Tutorial"*. May, 2005.

Nano Science and Technology Institute's Nano2005 Conference and Trade Show, Anaheim, CA. *"Tumor Targeted Nanocarriers for Drug and Gene Delivery"*. May, 2005.

Pfizer Central Research, Groton, CT. *"Polymeric Biomaterials and Targeted Delivery Systems"*. September, 2005.

Universidad Metropolitana (UMET), Department of Science and Technology, National Science Foundation Sponsored XIV Undergraduate Research Symposium. San Juan, PR. *"Nanotechnology for Medical Imaging and Therapy"*. September, 2005.

Strategic Research Institute, Inc., Cambridge, MA. Nanomedicine: Commercialization of Drug Discovery, Delivery, and Diagnostics Conference. *"Nanotechnology for Targeted Delivery of Drugs and Genes"*. October, 2005.

Nano Science and Technology Institute's Tutorial, Washington, DC *"Nanotechnology for Cancer Therapeutics – A Tutorial"* October, 2005.

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National Institute of Standards and Technology, Gaithersburg, MD. *"Nanotechnology for Cancer Imaging and Therapy"* December, 2005.

Alkermes, Inc., Cambridge, MA. *"Multi-Functional Nanotechnology for Imaging and Therapy"*. April, 2006.

Nano Science and Technology Institute's Tutorial, Washington, DC *"Nanotechnology for Cancer Therapeutics – A Tutorial"* May, 2006.

Nano Science and Technology Institute's Nano2006 Conference and Trade Show, Boston, MA. *"Nanotechnology in Drug Delivery: An Overview"*. May, 2006.

2006 Cancer Nanotechnology Conference, Paris, France. *"Nanotechnology for Tumor-Targeted Drug and Gene Delivery"*. May, 2006.

Northeastern University, Department of 2006 Pharmaceutical Sciences Research Showcase, Boston, MA. *"Multi-functional Nanosystems for Drug Delivery and Imaging"*. May, 2006.

National Cancer Institute, Center for Cancer Research, Nanobiology "Think Tank" Meeting, Frederick, MD. *"Multi-functional Nanosystems to Overcome Drug Resistance in Cancer"*. June, 2006.

Microfluidics, Inc., Newton, MA. *"Nanotechnology for Targeted Delivery of Drugs and Genes"*. June, 2006.

Wyeth Pharmaceuticals, Inc., Andover, MA. *"Nanotechnology and the Promise of Molecular Medicine"*. July, 2006.

Emory University, School of Medicine, Department of Ophthalmology, Atlanta, GA. *"Nanotechnology for Targeted Delivery of Drugs and Genes"*. July, 2006.

New Jersey Center for Biomaterials, Rutgers – the States University of New Jersey, Piscataway, NJ. *"Polymers for Tumor-Targeted Delivery and Modulation of Multidrug Resistance"*. August, 2006.

Accelrys Nanobiotechnology Seminar Series, Cambridge, MA. *"Nanotechnology for Targeted Delivery of Drugs and Genes"*. August, 2006.

Swiss House of Advanced Research and Education (SHARE), Consulate of Switzerland, Boston, MA. *"Nanotechnology for Medical Diagnosis and Treatment"*. September, 2006.

American Academy of Nanomedicine 2nd Annual Meeting, Washington, DC. *"Nanotechnology for Targeted Drug and Gene Delivery"*. September, 2006.

Epic Therapeutics, Inc., Norwood, MA. *"Nanotechnology for Targeted Delivery of Drugs and Genes"*. September, 2006.

12th Samsung International Symposium on Molecular Medicine, Seoul, Korea. *"Multi-functional Nanosystems for Tumor-Targeted Drug and Gene Delivery"*. September, 2006.

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Nanotechnology 2006 Conference, Rensselaer Polytechnic Institute, Troy, NY. *Multi-functional Nanosystems for Targeted Drug and Gene Delivery*". September, 2006.

Missouri Nanotechnology Alliance – 3rd Annual Meeting, Columbia, MO. *"Multi-functional Nanosystems for Tumor-Targeted Drug and Gene Delivery"*. October, 2006.

Cambridge Healthtech Institute's Targeted Nanodelivery Conference, Baltimore, MD. *"Multi-functional Nanosystems to Overcome Drug Resistance in Cancer"*. October, 2006.

Oncogene Science – A Bayer Healthcare Company, Cambridge, MA *"Nanomedicine: Realizing the Potential for Early Cancer Diagnosis and Molecular Therapy"*. October, 2006.

Northeastern University, Department of Chemistry and Chemical Biology, Boston, MA. *"Multi-functional Nanosystems for Imaging and Drug Delivery"*. November, 2006.

New Jersey Center for Biomaterials – 2nd Annual , Rutgers - The State University of New Jersey, New Brunswick, NJ. *"Multi-functional Nanosystems for Drug and Gene Delivery"*. November, 2006.

American College of Veterinary Pathologists and American Society for Veterinary Clinical Pathology Annual Meeting, Tucson, AZ. *"Nanotechnology for Medical Imaging and Therapy"*. December, 2006.

National Institutes of Health, National Cancer Institute's, Drug Development and Therapeutics Committee, Bethesda, MD. *"Multifunctional Nanosystems to Overcome Drug Resistance in Cancer"*. January, 2007.

Millennium Pharmaceuticals, Inc., Cambridge, MA. *"Nanotechnology Applications in Translational Oncology"*. January, 2007.

Harvard-MIT Health Science and Technology Program, MIT, Cambridge, MA. *"Nanotechnology Applications in Cancer Therapy"*. February, 2007.

New Jersey Center for Biomaterials, Rutgers - The State University of New Jersey, New Brunswick, NJ. *"Polymer Libraries for Tumor-Targeted Delivery and Modulation of Multidrug Resistance"*. March, 2007.

Strategic Research Institute's 2nd Annual Nanomedicine Conference, Washington, DC. *"Nanotechnology for Tumor-Targeted Delivery of Drugs and Genes"*. March, 2007.

Materials Research Society, 2007 Spring Meeting, San Francisco, CA. *"Pre-Clinical In Vivo Efficacy and Safety Studies – a Tutorial"*. April, 2007.

Materials Research Society, 2007 Spring Meeting, San Francisco, CA. *"Multifunctional Nanosystems for Targeted Drug and Gene Delivery"*. April, 2007.

American Association of Pharmaceutical Scientists, Northeast Regional Discussion Group Annual Meeting, Rocky Hill, CT. *"Micro- and Nanotechnology for Oral Drug and Gene Delivery"*. April, 2007.

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Genzyme Pharmaceuticals, Inc. – Drug and Biomaterials R&D, Waltham, MA. *“Nanotechnology Applications in Translational Oncology”*. April, 2007.

Vertex Pharmaceuticals, Inc., Cambridge, MA. *“Nanotechnology Applications in Translational Oncology”*. April, 2007.

Dartmouth College, Thayer School of Engineering, Hanover, NH. *“Cancer Nanomedicine: Potential for Targeted Delivery and Molecular Medicine”*. May, 2007.

2007 Association for Research in Vision and Ophthalmology Annual Meeting, Fort Lauderdale, FL. *“Nanotechnology in Advanced Drug Delivery: An Overview”*. May, 2007.

2007 Biotechnology Industry Organization Annual Conference, Cancer Nanotechnology for Early Diagnosis and Therapy Symposium, Boston, MA. *“Multifunctional Nanosystems for Tumor-Targeted Drug and Gene Delivery”*. May, 2007.

Northeastern University, Department of Pharmaceutical Sciences 2007 Research Showcase, Boston, MA. *“Systemic and Oral Therapeutic Gene Delivery with Non-Viral Vectors”*. May, 2007.

2007 Cancer Nanotechnology Conference, Paris, France. *“Multifunctional Nanosystems for Tumor-Targeted Drug and Gene Delivery”*. June, 2007.

Wellman’s Photomedicine Center, MA General Hospital, Boston, MA. *“Nanotechnology for Cancer Imaging and Therapy”*. July 2007.

National Cancer Institute, National Institutes of Health. Frederick, MD. *“Multifunctional Nanosystems to Overcome Drug Resistance in Cancer”*. July 2007.

Cerulean (Tempo) Pharmaceuticals, Inc., Cambridge, MA. *“Nanotechnology Applications in Translational Oncology”*. September 2007.

Tufts University – New England Medical Center, Molecular Oncology Research Institute, Boston, MA. *“Nanotechnology Applications in Translational Oncology”*. September 2007.

Merck Research Laboratories, Boston, MA. *“Nanotechnology Applications in Translational Oncology”*. September 2007.

2007 Boston Society for Advanced Therapeutics, Annual Meeting, Harvard Medical School, Boston, MA. *“Nanotechnology for Targeted Delivery of Drugs and Genes”*. September 2007.

Second Annual National Cancer Institute’s Nanotechnology in Cancer Alliance’s Principal Investigators Meeting, Chapel Hill, NC. *“Multifunctional Nanoparticles to Overcome Tumor Drug Resistance”*. October 2007.

Northeastern University, University’s Board of Trustee’s Annual Meeting, Boston, MA. *“Nanomedicine: Opportunity for Targeted Imaging and Drug Delivery”*. October, 2007.

Dartmouth College, Thayer School of Engineering, 8th Annual Nanomaterials Conference, Hanover, NH. *“Nanotechnology for Cancer Specific Drug and Gene Delivery”*. October, 2007.

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The Fifth Annual Nanomedicine and Drug Delivery Symposium (NanoDDS), Boston, MA
"Multifunctional Nanotherapeutic Strategies for Drug and Gene Delivery". November, 2007.

University of Central Florida, Nano Science and Technology Center, Orlando, FL. *"Nanotechnology Applications in Translational Oncology"*. November, 2007.

Dartmouth Medical School, Hanover, NH. *"Nanotechnology Applications in Translational Oncology"*. December, 2007.

University of South Carolina, Department of Pharmaceutical Sciences, College of Pharmacy, Columbia, SC. *"Nanomedicine: Opportunity for Translation of Molecular Therapies"*. February, 2008.

Medical University of South Carolina, School of Pharmacy, Charleston, SC. *"Nanomedicine: Opportunity for Translation of Molecular Therapies"*. February, 2008.

IQPC, The Future of Nanotechnology for Targeted Drug Delivery Conference, Boston, MA. *"Nanotechnology Applications in Translational Oncology"*. February, 2008.

Novartis Institutes for Biomedical Research, Cambridge, MA. *"Advances in Oral Drug and Gene Delivery Systems"*. April, 2008.

Museum of Science, Boston, MA. *"Nanomedicine: Realizing the Potential for Targeted Cancer Therapy"*. April, 2008.

Boston University, College of Engineering, 2008 Emerging Technology and Best Practices Seminar Series Nanotechnology in Medicine: From Diagnostics to Therapeutics Program, Boston, MA. *"Advances in Nanotechnology for Drug and Gene Delivery"*. April, 2008.

Microfluidics Corporation, Newton, MA. *"Nanotechnology for Targeted Imaging and Drug Delivery"*. April, 2008.

Atrium Medical Corporation, Hudson, NH. *"Advances in Nanotechnology for Drug and Gene Delivery"*. April, 2008.

First European Conference for Clinical Nanomedicine, Basel, Switzerland. *"Polymeric Nanosystems for Targeted Delivery of Drugs and Genes"*. May, 2008.

Mayo Clinic, Department of Biomedical Engineering, Rochester, MN. *"Nanotechnology Applications in Translational Oncology"*. September, 2008.

Pfizer – Research Technology Center, Cambridge, MA. *"Nanomedicine: Opportunity for Translation of Molecular Therapies"*. September, 2008.

Bio-Rad, Inc., Hercules, CA. *"Advances in Nanotechnology for Non-Viral Gene Delivery"*. October, 2008.

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Purdue University, School of Pharmacy, West Lafayette, IN. *"Multifunctional Nanosystems for Targeted Drug and Gene Delivery"*, November, 2008.

American Association of Pharmaceutical Scientists 2008 National Meeting, Atlanta, GA. *"Advances in Nanotechnology for Drug and Gene Delivery"*, November, 2008.

Materials Research Society, 2008 Fall Meeting, Boston, MA. *"Multifunctional Nanosystems for Cancer-Targeted Imaging and Drug Delivery"*. December, 2008.

Xavier University of Louisiana, College of Pharmacy, New Orleans, LA. *"Multifunctional Nanosystems for Targeted Drug and Gene Delivery"*. December, 2008.

Arqule, Inc., Waltham, MA. *"Nanotechnology Applications in Translational Oncology"*. January, 2009.

Indo-US Science and Technology Forum-Sponsored Cancer Nanotechnology Symposium, New Delhi, India. *"Multifunctional Nanosystems to Overcome Tumor Drug Resistance"*. February, 2009.

Panacea Biopharmaceuticals, Inc. New Delhi, India. *"Advances in Nanotechnology for Non-Viral Gene Delivery"*. February, 2009.

Institute of Genomics and Integrative Biology, New Delhi, India. *"Multi-functional Nanosystems for Targeted Drug and Gene Delivery"*. February, 2009.

Cadila Pharmaceuticals, LTD, Ahmedabad, India. *"Multi-functional Nanosystems for Targeted Drug and Gene Delivery"*. February, 2009.

Microfluidics Corporation, Newton, MA. *"Multifunctional Nanosystems for Targeted Imaging and Drug Delivery"*. February, 2009.

Strem Chemicals, Inc., Newburyport, MA. *"Nanotechnology Applications in Translational Oncology"*. February, 2009.

Microfluidics Corporation, Newton, MA. Webinar on *"Multifunctional Nanomedicine: Opportunity for Targeted Drug and Gene Delivery"*. May, 2009.

MA General Hospital, Department of Orthopedic Surgery and Orthopedic Oncology, Boston, MA. *"Multifunctional Nanosystems to Overcome Tumor Drug Resistance"*. July, 2009.

Microfluidics Corporation, Newton, MA. Roundtable Discussions with Scientific Board and Directors. *"Nanomaterial Technologies in Early Disease Diagnosis, Imaging and Therapy"*. July, 2009.

2009 American Association of Colleges of Pharmacy Annual Meeting, Boston, MA. *"Nanomaterial Technologies in Early Diagnosis, Imaging and Therapy"*. July, 2009.

Novartis Institute of Biomedical Research, Vaccine and Diagnostics Division, Cambridge, MA. *"Advances in Oral Non-Viral Gene Delivery Systems"*. July, 2009.

2009 Nano Business Alliance Conference, Chicago, IL. *"Nanotechnology in Early Diagnosis and Targeted Therapy"*. September, 2009.

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Roche Pharmaceuticals Partnering Event, Cambridge, MA. *"Nanotechnology in Early Diagnosis and Targeted Therapy"*. September, 2009.

Fifth Annual National Cancer Institute's Nanotechnology in Cancer Alliance's Principal Investigators Meeting, Manhattan Beach, CA. *"Multifunctional Nanoparticles to Overcome Tumor Drug Resistance"*. October 2009.

First Annual Conference of the American Society for Nanomedicine, Bolger Center, Potomac, MD. *"Multifunctional Nanosystems for Cancer Diagnosis and Therapy"*. October, 2009.

University of Wisconsin at Madison, School of Pharmacy, Madison, WI. *"Nanotechnology in Early Diagnosis and Targeted Therapy"*. November, 2009.

University of Illinois at Chicago, College of Pharmacy, Chicago, IL. *"Nanomedicine: Opportunity for Early Diagnosis and Targeted Therapy"*. January, 2010.

Langer Lab Seminar Series, MA Institute of Technology, Cambridge, MA. *"Nanotechnology in Early Diagnosis and Targeted Therapy"*. February, 2010.

University of Nebraska Medical Center, College of Pharmacy, Omaha, NE. *"Nanotechnology in Early Diagnosis and Targeted Therapy"*. March, 2010.

Canadian Society for Pharmaceutical Sciences 2010 Annual Meeting, Vancouver, British Columbia, Canada. *"Nanotechnology Applications in Cancer Diagnosis and Therapy"* June, 2010.

National Cancer Institute, Center for Cancer Research, Nano-Biology Program, Frederick, MD. *"Nanotechnology Applications in Cancer Diagnosis and Therapy"* June, 2010.

Stanford University, School of Medicine, Nano-Biotechnology Program Seminar Series, Stanford, CA. *"Multifunctional Nanosystems for Early Diagnosis and Targeted Therapy"*. June 2010.

American Chemical Society's National Meeting, Boston, MA. *"Multifunctional Nanosystems for Tumor Imaging and Therapy"*. August, 2010.

Second Annual Conference of the American Society for Nanomedicine, NIAID-Sponsored Symposium on Nanotechnology for HIV/AIDS. Bolger Center, Potomac, MD. *"Nanotechnology Advances in the Prevention and Treatment of HIV/AIDS"*. October, 2010.

Avila Therapeutics, Inc., Waltham, MA. *"Nanotechnology for Disease Diagnosis and Targeted Therapy"*. November, 2010.

2010 Annual National Cancer Institute's Nanotechnology in Cancer Alliance's Principal Investigators Meeting, Bethesda, MD. *"Combinatorial-Designed Nano-Platforms to Overcome Tumor Drug Resistance"*. November, 2010.

Center for Medicine and Innovative Technologies (CIMIT)-Wellcome Trust Joint Workshop on PTSD and TBI. Boston, MA. *"Strategies for Overcoming the Blood-Brain Barrier in CNS Therapies"*. January, 2011.

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15th International Symposium on Recent Advances in Drug Delivery Systems, University of Utah, Salt Lake City, UT. *"Multifunctional Nanosystems for Targeted Delivery of Molecular Therapies"*. February, 2011.

Keynote Presentation at the 2011 GRASP Annual Meeting, MA College of Pharmacy and Health Sciences, Boston, MA. *"Multifunctional Nanosystems for Molecular Medicine"*. June, 2011.

Fox Chase Cancer Center, Philadelphia, PA. *"Multifunctional Nanosystems to Overcome Tumor Drug Resistance"*. July, 2011.

2011 Annual National Cancer Institute's Nanotechnology in Cancer Alliance's Principal Investigators Meeting, Tutorial Presentation, Boston, MA. *"Nucleic Acid Therapeutics: Using DNA and Small Interfering RNA for Cancer"*. September 2011.

2011 Annual National Cancer Institute's Nanotechnology in Cancer Alliance's Principal Investigators Meeting, Boston, MA. *"Taming the Beast: Nanotechnology Solutions for Tumor Aggression"* September, 2011.

Eight Lohmann Therapie Systems (LTS) Academy Meeting, Bonn, Germany. *"Multi-functional Nanomedicines: From Diagnostics to Targeted Delivery"*. September, 2011.

Indiana University, Department of Biochemistry and Molecular Biology, Indianapolis, IN. *"Multi-functional Nanomedicines: From Cancer Diagnostics to Targeted Delivery"*. October, 2011.

University of Missouri at Columbia, Oncology Grand Rounds, Columbia, MO. *"Multi-functional Nanomedicines: From Cancer Diagnostics to Targeted Delivery"*. October, 2011.

American Association of Pharmaceutical Scientists (AAPS) 2012 annual meeting. Special symposium on *"Nano-Delivery Systems for Vaccines"*. Washington, DC. *"Multi-Compartmental Delivery Systems for Cancer Vaccination"*. October, 2011.

Carolina Center for Cancer Nanotechnology Excellence Symposium, University of North Carolina. Chapel Hill, NC. *"Multifunctional Nanosystems: From Diagnostic Imaging to Targeted Therapies"*. January, 2012.

2nd International Conference on Nanotechnology at Bio-Medical Interface. Amrita Centre for Nanosciences and Molecular Medicine, Kochi, Kerala State, India. *"Translational Cancer Nano-Medicine: From Diagnostic Imaging to Targeted Therapies"*. February, 2012.

Wayne State University, Department of Pharmaceutical Sciences, Applebaum College of Pharmacy and Allied Health. Detroit, MI. *"Translational Cancer Nano-Medicine: From Diagnostic Imaging to Targeted Therapies"*. March, 2012.

2012 Nano-Bio International Collaborative Conference, University of South Florida, Tampa, FL. *"Translational Cancer Nano-Medicine: From Diagnostic Imaging to Targeted Therapies"*. March, 2012.

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Tufts University, Center for Translational Science Institute (CTSI) Roundtable Discussions, Boston, MA. *"Delivery Strategies for CNS Therapies"*. March, 2012.

Tufts University School of Medicine, Cancer Center Seminar Program. Boston, MA. *"Translational Cancer Nano-Medicine: From Diagnostic Imaging to Targeted Therapies"*. April, 2012.

Canadian Society for Pharmaceutical Sciences 2012 Annual Meeting, Toronto, Ontario, Canada. *"Multi-Compartmental Lipid Delivery Systems for Cancer Vaccination"*. June, 2012.

2012 Nano Science and Technology Institute's Cancer Nanotechnology Symposium. Santa Clara, CA. *"Translational Cancer Nanomedicine: Multimodal Strategies to Overcome Tumor Drug Resistance"*. June, 2012.

University of Illinois at Urbana-Champaign 2012 BioSensing, BioActuation, and BioNanotechnology Summer Institute. Urbana-Champaign, IL. *"Translational Cancer Nano-Medicine: From Diagnostic Imaging to Targeted Therapies"*. August, 2012.

2012 American Association of Pharmaceutical Scientists Annual Meeting *"Tumor-Targeting Symposium"*. Chicago, IL. *Translational Cancer Nano-Medicine: Multimodal Strategies to Overcome Tumor Drug Resistance"* October, 2012.

2012 Annual National Cancer Institute's Nanotechnology in Cancer Alliance's Principal Investigators Meeting, Houston, TX. *"Combinatorial-Designed Self-Assembled Nano-Systems for Tumor-Targeted RNAi/Drug Therapy"* November, 2012.

University of Toronto, Leslie Dan School of Pharmacy, Toronto, Ontario, Canada. *"Translational Cancer Nano-Medicine: From Diagnostic Imaging to Targeted Therapies"*. November, 2012.

Merck Research Laboratories, Rahway, NJ. *"Translational Cancer Nano-Medicine: From Diagnostic Imaging to Targeted Therapies"*. November, 2012.

American Society of Health-Systems Pharmacists (ASHP) Midyear Meeting, *Spotlight on Science* Plenary Talk, Las Vegas, NV. *"Nanotechnology in Medicine: Very Tiny Solutions for Big Challenges"*. December, 2012.

National Cancer Institute, National Institutes of Health, Special symposium on "Dysregulated Endocytosis in Cancer". Bethesda, MD. *"Nanotechnology for Tumor-Targeted Drug and Nucleic Acid Delivery"*. January, 2013.

Harvard University, School of Engineering and Applied Sciences, Cambridge, MA. *"Translational Cancer Nano-Medicine: From Diagnostic Imaging to Targeted Therapies"*. January, 2013.

University of Connecticut, School of Pharmacy, Department of Pharmaceutical Sciences. Storrs, CT. *"Translational Cancer Nano-Medicine: From Diagnostic Imaging to Targeted Therapies"*. April, 2013.

Ferris State University, College of Pharmacy's 60th Annual Spring Pharmacy Seminar Series Keynote Presentation, Big Rapids, MI. *"Nanotechnology in Medicine: Very Tiny Solutions for Bio-Medical Challenges"*. May, 2013.

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University of Missouri Kansas City, School of Pharmacy, Department of Pharmaceutical Sciences. Kansas City, MO. *"Translational Cancer Nano-Medicine: From Diagnostic Imaging to Targeted Therapies"*. May, 2013.

First International Translational Nanomedicine Conference. Plenary Presentation. Northeastern University, Boston, MA. *"Translational Nano-Medicine: Diagnostics and Therapeutics for Cancer and Inflammatory Diseases"*. July, 2013.

University of Massachusetts Medical School, Program in Molecular Medicine, Worcester, MA. *"Translational Nano-Medicine: Targeted Therapeutics for Cancer and Inflammatory Diseases"*. September, 2013.

2013 Annual National Cancer Institute's Nanotechnology in Cancer Alliance's Principal Investigators Meeting, Bethesda, MD. *"Combinatorial-Designed Nano-Platforms: Opportunity for Targeted Delivery of Drugs and siRNA"* September, 2013.

Tufts University, Department of Biomedical Engineering, College of Engineering, Medford, MA. *"Translational Nano-Medicine: Targeted Therapeutics for Cancer and Inflammatory Diseases"*. March, 2014.

Johnson & Johnson Innovation Center, Cambridge, MA. *"Translational Nano-Medicine: Targeted Therapeutics for Cancer, Pain, and Inflammatory Diseases"*. April, 2014.

2014 Cambridge Healthtech Institute (CHI) Biologics Formulation and Delivery Summit, Keynote Presentation, Cambridge, MA. *"Translational Nano-Medicine: Targeted Therapeutics for Cancer and Inflammatory Diseases"*. May, 2014.

2014 Oligonucleotide and Peptide Therapeutics Symposium – TIDES, Providence, RI. *"CNS Delivery of Peptide Therapeutics"*. May, 2014.

Second International Translational Nanomedicine Conference. Plenary Presentation. Northeastern University, Boston, MA. *"Nanotechnology for CNS Delivery of Biological Therapeutics"*. July, 2014.

Second Annual Workshop on Micro- and Nano-Technologies for Medicine: Emerging Frontiers and Applications. MIT-Harvard Science and Technology Program and the Wyss Institute. Cambridge, MA. *"Translational Nano-Medicine: Targeted Therapeutics for Cancer and Inflammatory Diseases"*. July, 2014.

2014 Annual National Cancer Institute's Nanotechnology in Cancer Alliance's Principal Investigators Meeting, Bethesda, MD. *"Combinatorial-Designed Nano-Platforms: RNAi and Drug Co-Therapy in Resistant Tumors"* October, 2014.

Houston Methodist Research Institute's George and Angelina Kostas Research Center for Cardiovascular Nanomedicine Inaugural Symposium. Houston, TX. *"Targeted Therapeutic Delivery for Endothelial Dysfunction in Cardiovascular Diseases"*. October, 2014.

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University of Michigan, College of Pharmacy, Department of Pharmaceutical Sciences, Ann Arbor, MI. *"Translational Nano-Medicine: Targeted Therapeutics for Cancer and Inflammatory Diseases"*. November, 2014.

Purdue University, School of Pharmacy and Pharmacal Sciences, 12th Annual Garnet E. Peck Symposium, West Lafayette, IN. *"Translational Nano-Medicine: Targeted Therapeutics for Cancer and Inflammatory Diseases"*. February, 2015.

Henry Stuart Talks, London, UK. *"Nanotechnology for CNS Delivery of Biological Therapeutics"*. March, 2015.

Takeda Pharmaceuticals, New Frontier Science, Cambridge, MA. *"Nanotechnology for Systemic and Local GI Delivery"*. March, 2015.

Microfluidics, Inc., Westwood, MA. A webinar presentation on *"Nano-Emulsions for CNS Delivery of Biological Therapeutics"*. April, 2015.

New England Structural Biology Association (NESBA) Annual Symposium, Bentley University, Waltham, MA. Keynote presentation entitled *"Translational Nano-Medicine: Targeted Therapeutics for Pain, Cancer, and Inflammatory Diseases"*. May, 2015.

King Abdulaziz University, Faculty of Pharmacy, Jeddah, Saudi Arabia. Presentation to the graduating class of Doctor of Pharmacy students on *Pharmacy Career Day 2015* entitled *"Translational Nano-Medicine: Opportunities in Graduate Education and Research"*. May, 2015.

King Abdulaziz University, Faculty of Pharmacy, Jeddah, Saudi Arabia. Research presentation to the faculty and students entitled *"Translational Nano-Medicine: Tiny Solutions for Big Biomedical Challenges"*. May, 2015.

Tufts University Cancer Center 2015 Research Retreat, Cummings School of Veterinary Medicine at Tufts, Grafton, MA. *"Multimodal Nanotechnology Solutions for Drug Resistant Tumors"*. June, 2015.

Eight European Summit for Clinical Nanomedicine and Targeted Medicine, Basel, Switzerland. *"Macrophage-Targeted Nano-Delivery Systems for Anti-Inflammatory Therapy"*. June, 2015.

Third Annual Workshop on Micro- and Nano-Technologies for Medicine: Emerging Frontiers and Applications. MIT-Harvard Science and Technology Program and the Wyss Institute. Cambridge, MA. *"Advances in the Delivery of Cancer Vaccines and Therapeutics"*. July, 2015.

Northeastern University and Houston Methodist Research Institute Collaborative Meeting, Boston, MA. *"Targeted Nucleic Acid Delivery in Inflammatory Diseases"*. August, 2015.

Bioscience Seminar Program, Morsani College of Medicine, USF Health, University of South Florida, Tampa, FL. *"Translational Nano-Medicine: Targeted Therapeutics for Pain, Cancer, and Inflammatory Disease"*. September, 2015.

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Houston Methodist Research Institute's George and Angelina Kostas Research Center for Cardiovascular Nanomedicine Second Annual Symposium. Houston, TX. "*Targeted Delivery of Nucleic Acids for Inflammatory Diseases*". October, 2015.

Forsyth Institute, Cambridge, MA. "*Advances in Nanotechnology for Inflammatory Diseases*". January, 2016.

Dicerna Pharmaceuticals, Inc., Cambridge, MA. "*Translational Nano-Medicine: Targeted Therapeutics for Pain, Cancer, and Inflammatory Disease*". February, 2016.

Eight Bangalore India Nano Conference. Bangalore, Karnataka State, India. "*Translational Nano-Medicine: Targeted Therapeutics for Pain, Cancer, and Inflammatory Disease*". March, 2016.

2016 Annual SPIE Conference. Special symposium on Multifunctional Nanoparticles for Biomedical Research, Baltimore, MD. "*Multifunctional Nanoparticles for Nucleic Acid Therapy*". April, 2016.

2016 American Association of Pharmaceutical Scientists, National Biotechnology Conference, Boston, MA. "*Targeted Nano-Therapeutics for Drug Resistant Tumors*". May, 2016.

2016 Pharmaceutical Sciences Research Showcase, Northeastern University, Boston, MA. "*Exosome-Mediated Reprogramming of the Tumor Microenvironment*". May, 2016.

Engineering Conference International. Symposium on Nanotechnology in Medicine: From Molecules to Humans, Henstein, Austria. "*Translational Nano-Medicine: Targeted Therapeutics for Cancer and Inflammatory Disease*". July, 2016.

Fourth Annual Workshop on Micro- and Nano-Technologies for Medicine: Emerging Frontiers and Applications. MIT-Harvard Science and Technology Program and the Wyss Institute. Cambridge, MA. "*Macrophage Reprogramming in Cancer and Inflammatory Diseases*". July, 2016.

Third International Ovarian Cancer Symposium and International Symposium on Tumor Microenvironment and Therapy Resistance, University of Oklahoma Health Sciences Center, Oklahoma City, OK. "*Targeted Nano-Therapeutics for Drug Resistant Tumors*". August, 2016.

2016 Asian Polymer Association's International Conference on Advanced Polymers, Biomaterials, Bioengineering and Nano-Drug Delivery. Flic-En-Flac, Mauritius. "*Combinatorial-Designed Polymeric Nanosystems for Targeted Drug Delivery*". September, 2016.

University of Porto, Porto, Portugal. "*Translational Nano-Medicine: Targeted Therapeutics for Pain, Cancer, and Inflammatory Disease*". October, 2016.

Brown University, Department of Molecular Pharmacology, Physiology, and Biotechnology. Providence, RI. "*Targeting Nucleic Acid Base Therapeutics for Cancer and Inflammatory Diseases*". November, 2016.

2017 Systems Oncology Conference, Amrita Institute of Medical Sciences, Amrita Institute, Kochi, Kerala, India. "*Targeted Nano-Therapeutics for Drug Resistant Tumors*". March, 2017.

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University of Alberta, Faculty of Pharmacy and Pharmaceutical Sciences, Edmonton, Alberta, Canada. Invited presentation entitled "*Translational Nano-Medicine: Targeted Therapeutics for Pain, Cancer, and Inflammatory Diseases*". March, 2017.

Institute for Research and Medical Consultation (IRMC), Imam Abdulrahman bin Faisal University, Dammam, Saudi Arabia. "*Translational Nano-Medicine: Targeted Therapeutics for Pain, Cancer, and Inflammatory Diseases*". May, 2017.

Keynote presentation at the 91st American Chemical Society Colloid and Surface Science Symposium. City College of New York, New York, NY. "*Combinatorial-Designed Nano-Systems for Delivery of Nucleic Acid*". July, 2017.

Fifth Annual Workshop on Micro- and Nano-Technologies for Medicine: Emerging Frontiers and Applications. MIT-Harvard Science and Technology Program and the Wyss Institute. Cambridge, MA. "*Advances in CNS Delivery of Biological Therapeutics*". July, 2017.

Keynote presentation at the Applied Pharmaceutical Nanotechnology (APN) 2017 Conference, Broad Institute, Massachusetts Institute of Technology, Cambridge, MA. "*Translational Nano-Medicine: Targeted Therapeutics for Pain, Cancer, and Inflammatory Diseases*". October, 2017.

Seminar presentation in the Department of Biochemistry and Molecular and Cellular Biology, Georgetown University Medical Center, Washington, DC. "*Delivery of Nucleic Acid Therapeutics for Refractory Tumors*". October, 2017.

Seminar presentation in the Department of Chemistry, Kennedy College of Sciences, University of Massachusetts at Lowell, Lowell, MA. "*Advances in Systemic and Oral Nucleic Acid Therapeutic Delivery*". November, 2017.

Plenary presentation at the End-2-Cancer Symposium on Emerging Nanotechnology and Drug Delivery for Cancer. University of Oklahoma Health Sciences Center, Oklahoma City, OK. "*Reprogramming the Tumor Microenvironment by Exosomal Transfer of Nucleic Acids*". December, 2017.

Institute for Research and Medical Consultation (IRMC), Imam Abdulrahman bin Faisal University, Dammam, Saudi Arabia. "*Nanotechnology for the Treatment of Resistant Tumors*". March, 2018.

Institute for Research and Medical Consultation (IRMC), Imam Abdulrahman bin Faisal University, Dammam, Saudi Arabia. "*Nanotechnology for CNS Delivery of Biological Therapies*". March, 2018.

Institute for Research and Medical Consultation (IRMC), Imam Abdulrahman bin Faisal University, Dammam, Saudi Arabia. "*Nanotechnology in Cardiovascular Medicine*". March, 2018.

American Chemical Society and American Association of Pharmaceutical Scientists - 2018 Drug Design and Delivery Symposium Webinar Series. "*Advanced Nano-Delivery Systems: Facilitating Tumor Delivery and Mitigating Resistance*". May, 2018.

Stony Brook University Institute of Chemical Biology and Drug Discovery (ICB & DD) 2018 Symposium on "Frontiers of Nanomedicine: Drug Delivery, Therapeutics, and Diagnosis" Keynote

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Presentation. Stony Brook, NY *"Integrated Nano-Medicine for Cancer and Inflammatory Diseases"*. October, 2018.

University of Massachusetts Medical School, Department of Biochemistry and Molecular Pharmacology, Worcester, MA. *"Targeted Delivery of Nucleic Acid Therapy for Cancer and Inflammatory Diseases"*. November, 2018.

Chapman University, College of Pharmacy. Irvine, CA. *"Translational Nano-Medicine: Targeted Therapeutics for Pain, Cancer, and Inflammatory Disease"*. November, 2018.

University of Santiago de Compostela, "Frontiers in Science" Seminar Series, Keynote Presentation. Santiago de Compostela, Spain. *"Translational Nano-Medicine: Targeted Therapeutics for Pain, Cancer, and Inflammatory Diseases"*. January, 2019.

Astra Zeneca, Waltham, MA. *"Advances in Nano-Delivery of Nucleic Acid Therapies"*. August, 2019.

17th Annual Nanomedicine and Drug Delivery Technology Symposium (NanoDDS). Massachusetts Institute of Technology, Cambridge, MA. *"Macrophage Reprogramming with Nano-Delivery for Cancer and Inflammatory Diseases"*. September, 2019.

University of Nebraska Medical Center, College of Pharmacy. Omaha, NE., *"Translational Nano-Medicine: Targeted Therapeutics for Pain, Cancer, and Inflammatory Diseases"*. October, 2019.

St. Johns University, College of Pharmacy and Health Sciences, Queens, NY. *"Targeted Delivery of Biological Therapies for Cancer and Inflammatory Diseases"*. October, 2019.

2019 American Association of Pharmaceutical Scientists Annual Meeting, San Antonio, TX. *"Role of Protein Corona on Oligonucleotide Delivery and Transfection with Lipid Nanoparticles"*. November, 2019.

INTELLECTUAL CONSULTANCY

GelTex Pharmaceuticals, Inc., Waltham, MA. A medium sized pharmaceutical company that is marketing non-absorbable polymeric materials as therapeutic agents. I have consulted on pharmaceutical product development with GelTex's polymeric materials from May 1997 to June 2000.

FzioMed, Inc., San Luis Obispo, CA. A start-up medical device company intending to market polymeric materials to prevent post-surgical adhesions and thrombus formation. I have consulted on improving blood compatibility of the polymeric materials developed by FzioMed from October 1996 to April 1999.

EOS Pharmaceutical Corporation, Natick, MA. A start-up contract formulation company with domestic and international clients. I have consulted EOS Pharmaceuticals on novel bioadhesive polymeric materials for drug delivery from June 1997 to September 2001.

Biopolymer Technologies International, Inc., Westborough, MA. A start-up biotechnology company specializing in the development of polymer-based therapeutics and nutraceuticals. I have consulted for Biopolymer Technologies International from December 1997 to July 1999.

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Braintree Laboratories, Inc., Braintree, MA. A medium sized pharmaceutical company developing various products, including phosphate binders, poly(ethylene glycol)-based laxatives, and gastric lavage agents. I have consulted for Braintree Laboratories from September 1999 to June 2003.

Catalyst Oncology, Inc., Providence, RI. A biotechnology start-up company, supported by the Slater Foundation, to develop novel target-specific anticancer drugs. I have consulted Catalyst Oncology on anticancer drug delivery issues from December 2003 to December 2004.

Cytogel, Inc., Stonington, CT. Cytogel is a small pharmaceutical company focusing on hydrogel drug delivery technologies. I have consulted Cytogel on their hydrogel delivery platforms from September, 2004 to April 2005.

LifeScan, Inc., Milpitas, CA. LifeScan is a Johnson and Johnson subsidiary developing diagnostic systems for diabetes. I have been consulting LifeScan on their diabetes monitoring technologies from August, 2005 to May 2006.

Boston Scientific Corporation, Marlborough, MA. A large-cap medical device company that manufactures drug-coated stents, catheters, and embolic microspheres. I have consulted Boston Scientific on drug delivery technologies from October, 2003 to September, 2006.

Novavax, Inc., Columbia, MD. A medium-sized pharmaceutical company that focuses on women's healthcare market. I have consulted Novavax on their micellar nanoparticle and other delivery platforms from February, 2004 to December, 2006.

Scientia Advisors, LLC, Cambridge, MA. Scientia Advisors is an international management and strategy consulting firm with a concentration in biotechnology and life sciences. I provide intellectual consulting on polymeric drug delivery technologies. I have consulted Scientia Advisors from July, 2008 to May, 2009.

Cequent Pharmaceuticals, Inc., Cambridge, MA. Cequent Pharmaceutical is small company interested in development of proprietary Transkingdom RNA interference technology. I provide consulting service in formulation development and oral delivery. I have consulted Cequent Pharmaceuticals from May, 2007 to December, 2008.

Marine Polymer Technologies, Inc., Burlington, MA. A medium sized biotechnology/medical device company developing poly(acetyl-D-glucosamine)-based products. I have been consulting Marine Polymer on drug formulation and delivery technologies from September 2002 to June, 2007.

Genzyme Pharmaceuticals – Biomaterials and Drug Development Group, Waltham, MA. Genzyme is a medium sized pharmaceutical company with interest in polymeric drug development. I provide intellectual consultation on polymeric biomaterials and drug delivery systems. I provided consultation on drug delivery and nanotechnology from August, 2007-July, 2008.

Grayhead Associates, Wellesley, MA. Grayhead Associates is an international management consulting firm that assists its clients to capitalize on their technological resources and

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entrepreneurial spirit. I have been consulting Greyhead Associates on biomedical nanotechnology and drug development technologies from October, 2005 to May, 2009.

Vertex Pharmaceuticals, Inc., Cambridge, MA. Vertex is a medium sized pharmaceutical company developing a number of proprietary therapeutics in cancer, inflammation, and infectious diseases. I provide intellectual consultation on drug delivery and nanotechnology. I have been consulting Vertex from January, 2008 to April, 2010.

BioCure, Inc., Norcross, GA. BioCure is a medium-sized biomedical device company developing polymer nanotechnology for imaging and drug delivery applications. I have been consulting BioCure on their nanotechnology research portfolio from August 2006 to June, 2010.

Cerulean Pharmaceuticals, Inc., (previously Tempo Pharmaceuticals Inc.), Cambridge, MA. Cerulean Pharmaceutical is a startup company interested in development of proprietary multi-modal polymeric nanoparticle technology. I provide consulting service in nanoparticle formulations and preclinical studies. I have been consulting Cerulean Pharmaceuticals from September, 2008 to June, 2016.

Takeda Pharmaceuticals, Inc., Cambridge, MA. Takeda is a large multi-national pharmaceutical industry interested in development of nucleic acid therapeutics. I serve as a consultant in the area of nucleic acid formulations for both oral and systemic delivery for variety of disease targets from May, 2015 to December 2016.

Sun Pharmaceuticals Advanced Research Centre (SPARC), Baroda, India. SPARC is a research and development of arm of multinational Sun Pharmaceuticals, Inc. I am involved in consultation on oral and systemic controlled release drug delivery systems for various therapeutic areas from February, 2016 to December, 2017.

Summit Street Medical, LLC, Wallingford, CT. Summit Street is a start-up company involved in repurposing existing therapeutics using novel drug formulation and delivery devices. I am involved in consultation on systemic drug delivery systems for various therapeutic areas from September, 2017 to June, 2018.

Thompson-Reuters Group (RTG), Washington, DC. RTG provides expert witness, intellectual consulting, and professional presentation services to many diverse groups of clients. I serve as a consultant in the area of pharmaceutical product development, biomaterial science and applications, and nano-medical technologies from February, 2004 to present.

IMS Expert Services, Pensacola, FL. IMS provides expert witness and intellectual consulting services to many diverse groups of clients. I serve as a consultant in the area of pharmaceutical product development, biomaterial science and applications, and nano-medical technologies from June, 2011 to present.

Rubin-Anders Consulting, Boston, MA. Rubin-Anders provides expert witness and intellectual consulting services to many diverse groups of clients. I serve as a consultant in the area of pharmaceutical product development, biomaterial science and applications, and nano-medical technologies from March, 2013 to present.

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Rubin-Anders Consulting, Boston, MA. Rubin-Anders provides expert witness and intellectual consulting services to many diverse groups of clients. I serve as a consultant in the area of pharmaceutical product development, biomaterial science and applications, and nano-medical technologies from March, 2013 to present.

TEACHING EXPERIENCES

Courses Currently Teaching (2003 – Present)

Doctor of Pharmacy Program

Pharmaceutics 2 (PHSC 3412, 4 SH): Theoretical course on the physicochemical properties of the drug product and their influence on development of pharmaceutical formulations and delivery offered under the semester calendar (for 16 weeks). I coordinate and teach 60% of this course to 4th year students. Approximate class size is about 150 students each year.

Directed Study (PSC U921, 4 SH): An elective course for professional pharmacy students interested in performing research under a faculty advisor.

Graduate Program in Pharmaceutical Sciences:

Advanced Drug Delivery Systems (PSC G254, 3 SH): A graduate course for MS and PhD students in Pharmaceutical Sciences and other departments across campus focusing on novel drug delivery systems such as polymeric and lipid nano-formulations for drug, gene, vaccine, and siRNA delivery. The course is taught to 50-60 students each Fall and I coordinate and teach 40% of the lectures.

Drug Design, Evaluation, and Development (PSC G210, 2 SH): A graduate level comprehensive course on drug discovery, development, and evaluation from an industrial perspective. I teach about 20% of the course to approximately 50-60 MS and PhD students in the Fall semester each year.

Pharmaceutical Science Seminar (PSC G200, 1 SH): A course on graduate seminar and journal club presentations for development of scientific skills for MS and PhD students in the department. I coordinate and teach 100% of the course for approximately 20-30 MS and PhD students in the Fall semester each year.

Pharmaceutical Science Internship (PSC G401, 1 SH): Coordinator of industrial internship opportunities for graduate students in Pharmaceutical Science. Each year in the Summer, I assist 3-5 MS and PhD students in securing an internship position and evaluating their progress.

Interdisciplinary Graduate Programs:

Introduction to Biotechnology (INT G120, 2 SH): An interdisciplinary graduate course offered to students in the Professional MS program in Biotechnology in the Fall semester each year. I provide 10% effort to this course.

Introduction to Nanomedicine Science and Technology (INT G270, 2 SH): An interdisciplinary graduate course offered under the Nanomedicine Science and Technology IGERT program in the Fall semester of each year. I provide 20% effort to this course.

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Nanosystems Design for Biomedical Applications (INT G370, 2 SH): An interdisciplinary graduate course offered under the Nanomedicine Science and Technology IGERT program in the Spring semester of each year. I provide 20% effort to this course.

Seminars in Nanomedicine (INT G371, 1 SH): An interdisciplinary graduate course offered under the Nanomedicine Science and Technology IGERT program in the Fall semester of each year. I coordinate this seminar course and provide 100% effort.

Courses Previously Taught***Pharm.D. Program:***

Pharmaceutical Calculations (PCT 1240, 4 QH): Basic prescription interpretation and calculations for second year pharmacy students.

Dosage Forms (PMD 1323, 4 QH): Theoretical course on pharmaceutical product development, characterization, and quality control issues taught to the third year pharmacy students.

Dosage Forms Laboratory (PCT 1300, 2 QH): A complementary laboratory course for Dosage Forms on prescription compounding skills.

Physical Pharmacy (PMD 1400, 4 QH): Theoretical course on the physicochemical properties of the drug product and their influence on development of pharmaceutical formulations and delivery.

Physical Pharmacy Laboratory (PCT 1320, 2 QH): A complementary laboratory course to Physical Pharmacy on analytical and experimental methods for testing of pharmaceutical products for quality control.

Biopharmaceutics and Pharmacokinetics (PMD 1410, 4 QH): Introduction to biopharmaceutics and pharmacokinetic principles, application of compartmental and non-compartmental modeling for analysis of data, and interpretation of pharmacokinetic data in clinical pharmacy practice.

Graduate Program:

Advanced Physical Pharmacy (PCT 3200, 2 QH): A graduate level physical pharmacy course that with emphasis on physicochemical characterization of drug products.

Advanced Drug Delivery Systems (PCT 3300, 3 QH): A graduate level course on formulation and evaluation of advanced drug delivery systems including polymeric systems, liposomes, micelles, protein and peptide delivery, and DNA delivery systems.

TEACHING-RELATED ACCOMPLISHMENTS

Professional Science Masters (PSM) Degree Program in Biomedical Nanotechnology: Working with Pharmaceutical Sciences, School of Law, and College of Business faculty, I have developed a new Professional Science Masters program in Biomedical Nanotechnology. The program will offer terminal MS degree with didactic scientific, patent law, and entrepreneurship courses along with practical internship experience. The first class was admitted in Fall, 2013.

“Non-Traditional” (Industrial) PhD Program in Pharmaceutical Sciences: For students who have completed an MS degree in Pharmaceutical Sciences or related field and are currently working in

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industry, we have implemented a new 'non-traditional' PhD program that waives their didactic course-work. With permission from the corporate sponsors, students enroll in the PhD program and start thesis project under a faculty mentor, while still keeping their "day job" with the industry. The program was started in 2009 and graduated the first cohort of PhD students in 2012.

IGERT Training Grants for Doctoral Training in Nanomedicine - Phase 1 and 2: With funding from the National Cancer Institute and the National Science Foundation (NSF), we have established an Interdisciplinary Graduate Education, Research and Training (IGERT) program. I am involved in the development and implementation of the Nanomedicine Science and Technology doctoral program. The program will admit interdisciplinary fellows who will take didactic courses, participate in internship opportunity, and carry out dissertation project in nanomedicine-related project. The program started in Fall, 2005. Phase 2 program started in Fall 2010 with funding from the NSF.

Multi-Track Professional Science Masters (PSM) Degree Program in Biotechnology: With the support of the Alfred P. Sloan Foundation, I have worked with faculty members from the Biology and Chemical Engineering Departments at Northeastern University to develop and implement an interdisciplinary Professional MS degree program in Biotechnology with tracks in Molecular Biotechnology, Pharmaceutical Biotechnology, and Engineering Biotechnology. The program started in the Fall of 2003.

Applied Physical Pharmacy Textbook: In collaboration with Professor Beverly Sandmann of Butler University, I have authored "*Applied Physical Pharmacy*" textbook specifically geared to pharmacy students and practitioners. The book contains physical chemical concepts in drug product design with examples that are relevant to practice. The textbook was published in November 2002. In collaborations with Professors Thomas Cook from Tauro College of Pharmacy and W. Cary Mobley from University of Florida College of Pharmacy, a second edition of the textbook is in development for anticipated publication in early 2014.

Problem-Based Undergraduate Pharmaceutics Textbook: In collaboration with other pharmaceutics faculty members across the U.S. and Canada, I have authored cases for a textbook entitled "*Cases in Pharmaceutics for Problem-Based Learning and Problem Solving*" edited by Wendy C. Duncan-Hewitt and David L. Mount of the University of Toronto, Canada.

Pharmaceutics Laboratory Exercises Database and CD-ROM: I have contributed eight pharmaceutics laboratory exercises to the database and CD-ROM initiative of David L. Mount and others.

Pharmaceutics Instructional Materials on World-Wide Web: With funding from the Dean's "Excellence in Teaching" initiative, I have developed pharmaceutics instructional materials on the Internet. These pages can be accessed through the World-Wide Web at "<http://www.pharmsci.neu.edu/Courses/courses.html>".

Computer-Aided Pharmaceutics Instruction: I am involved in various aspects of promoting and developing computer aids and tutorial programs for undergraduate pharmaceutics courses. In addition, I strongly advocate the use of pharmacy resources that are available on the Internet.

NAPLEX Review: In the Spring quarter of every year, I provide an extensive review of Calculations, Physical Pharmacy, and Dosage Forms to the senior students who are planning to take the National Board of Pharmacy Licensing Examination (NAPLEX). In addition, I also provide a review

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of compounding skills to those students taking their NAPLEX exam in states that have a wet-lab section (e.g., New York, Maryland, Wisconsin, etc.).

RESEARCH ADVISING***Visiting Scientists and Research Fellows***

Mr. Srinivas Ganta	PhD Candidate	University of Auckland Auckland, New Zealand July, 2007 – October, 2007
Dr. Pauline Pei Li	Associate Professor	Hong Kong Polytechnic University, Hong Kong, August, 2007
Dr. Wei Duan Medicine	Associate Professor	Daikin University, School of Melbourne, Victoria, Australia, May, 2008
Dr. Cristina Dehelean Medicine	Professor	Victor Babes University of and Pharmacy, Timisoara, Romania, November, 2008
Ms. Jose das Neves College of Pharmacy,	PhD Candidate	University of Porto, Porto, Portugal September, 2009 – March, 2010
Ms. Sharareh Adeli Sciences, Tehran,	PhD Candidate	Tehran University of Medical Iran. November, 2009 – March, 2010
Dr. Satheesh Elangovan Boston, MA	Research Fellow	The Forsyth Dental Institute, November, 2009 – May, 2010
Ms. Meghna Talekar	PhD Candidate	University of Auckland Auckland, New Zealand July, 2011 – December, 2011
Dr. Florence Gattacceca Pharmacy	Assistant Professor	Montpellier University, Faculty of Montpellier, Cedex, France August, 2012 – August, 2013 June, 2016 – September, 2016
Pharmacy	Associate Professor	Aix- Marseille University, Faculty of Marseille, France

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July, 2018 – September, 2018

Ms. Ana Vanessa Nascimento
College of Pharmacy,

PhD Candidate

University of Porto,

Porto, Portugal

August, 2012 – October, 2014

Ms. Minah Iqbal

MS in Biotechnology

Columbia University

New York, NY

January, 2015 – May, 2015

Dr. Sundus Tewfik

Professor

London Metropolitan University

London, United Kingdom

March, 2016 – April, 2016

Ms. Smrithi Padmakumar

PhD Candidate
Sciences

Amrita Institute of Medical

Kochi, Kerala, India

September, 2017 – March, 2018

Ms. Sevde Altuntas

PhD Candidate

Tobb University of Economics
and Technology

Ankara, Turkey

November, 2017 – August, 2018

Ms. Flavia Sousa
Pharmacy,

PhD Candidate

University of Porto, College of

Porto, Portugal

February, 2018 – August, 2018

Research Faculty and Post-Doctoral Associates

Dr. Curtis F. Crasto

Post-Doctoral Associate

July, 2002 – May, 2004,
under the Nanomedicine
Consortium

Dr. Dinesh B. Shenoy
2005

Associate Research Scientist

June, 2003 – December,

Dr. Sandip K. Tiwari

Post-Doctoral Associate

August, 2004 – June, 2006

Dr. Tushar K. Vyas

Post-Doctoral Associate

December, 2005 – December, 2006

Dr. Aliasgar Shahiwala
2007

Post-Doctoral Associate

August, 2006 – August,

Dr. Harikrishna Devalapally
February, 2008

Post-Doctoral Associate

November, 2005 –

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Dr. Christina Kriegel 2010	Post-Doctoral Associate	September, 2008 – June,
Dr. Srinivas Ganta	Post-Doctoral Associate Associate Research Scientist	April, 2008 – February, 2010 March, 2010 – November, 2010
Dr. Sampath Abeylath	Post-Doctoral Associate	March, 2010 – May, 2011
Dr. Tatyana Chernenko	Post-Doctoral Associate	May, 2010 – March, 2012
Dr. Ming Chen	Associate Research Scientist	July, 2011 – March, 2012
Dr. Qiong-Lin Zhou	Research Assistant Professor	December, 2010 – August, 2012
Dr. Srinivas Reddy Boreddy	Associate Research Scientist	August, 2012 – January, 2013
Dr. Dattatri Nagesha	Post-Doctoral Associate Coordinator of the IGERT Nanomedicine Program	July, 2004 – May, 2013
Dr. Arun K. Iyer	Post-Doctoral Associate Associate Research Scientist Research Assistant Professor	May, 2008 – December, 2008 December, 2010 – June, 2012 July, 2012 – January, 2014
Dr. Sanjib Bhattacharya	Post-Doctoral Associate	April, 2014 – June, 2014
Dr. Malav Trivedi	Post-Doctoral Associate	July, 2014 – December, 2014
Dr. Amit Singh 2015	Associate Research Scientist	May, 2011 – January,
Dr. Meghna Talekar	Post-Doctoral Associate	April, 2013 – April, 2015
Dr. Than-Huyen Tran October, 2015	Post-Doctoral Associate	December, 2013 –
Dr. George Matthiolampakis	Post-Doctoral Associate	August, 2014 – May, 2016
Dr. Gulzar Ahmad 2017	Post-Doctoral Associate	December, 2015 – November,
Dr. Neha Parayath	Post-Doctoral Associate	April, 2016 – May, 2018
Dr. Harkiranpreet Dhaliwal	Post-Doctoral Associate	August, 2016 – October, 2018
Dr. Ahmed Radwan 2018	Medical Fellow	March, 2016 – August,
Hospital,	(Joint with Dr. Ali Hafezi-Moghadam, Brigham and Women's	

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	Boston, MA)	
	Visiting Scholar	September, 2018 - Present
Dr. Smrithi Padmakumar	Post-Doctoral Associate	May, 2019 – Present
Dr. Maie Taha	Post-Doctoral Associate	June, 2019 – Present

Doctoral Students

Mr. Radi Hejazi	Ph.D. in Pharmaceutical Science – Pharmaceutics and Drug Delivery (Graduated, May 2003) Thesis Title: <i>Stomach-Specific Delivery of Tetracycline-Chitosan Microspheres for the Treatment of Helicobacter pylori Infection.</i>
Ms. Goldie Kaul	Ph.D. in Pharmaceutical Science – Pharmaceutics and Drug Delivery (Graduated, August 2004) Thesis Title: <i>Long-Circulating Poly(Ethylene Glycol)-Modified Gelatin Nanoparticles for Tumor-Targeted Gene Delivery.</i>
Ms. Sushma Kommareddy	Ph.D. in Pharmaceutical Science – Pharmaceutics and Drug Delivery (Graduated, May 2006) Thesis Title: <i>Gelatin-Based Nanoparticulate Vectors for Tumor-Targeted Therapeutic Gene Delivery</i>
Mr. Mayank Bhavsar	Ph.D. in Pharmaceutical Science – Pharmaceutics and Drug Delivery (Graduated, August 2007) Thesis Title: <i>Oral Gene Therapy for Inflammatory Bowel Disease Using Nanoparticles-in-Microsphere Hybrid Delivery System</i>
Ms. Lilian van Vlerken	Ph.D. in Pharmaceutical Science – Pharmaceutics and Drug Delivery IGERT Nanomedicine Fellow (Graduated, February 2008) Thesis Title: <i>Modulation of Multidrug Resistance in Cancer Using Polymer-Blend Nanoparticles</i>
Mr. Luis Brito	Ph.D. in Pharmaceutical Science – Pharmaceutics and Drug Delivery IGERT Nanomedicine Fellow (Graduated, December 2008) Thesis Title: <i>Local Endothelial Nitric Oxide Synthase Gene Delivery and Transfection with Lipopolyplexes for the Treatment of Coronary Restenosis</i>
Ms. Lara Jabr-Milane	Ph.D. in Pharmaceutical Science – Pharmaceutics and Drug Delivery

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IGERT Nanomedicine Fellow
(Graduated, June 2010)

Thesis Title: *Tumor Hypoxia, Warburg's Effect, and Drug Resistance: Modulation of Aerobic Glycolysis Using Combination Paclitaxel/Lonidamine Therapy Delivered in Targeted Polymeric Nanoparticles*

Mr. Mayur Kalariya Ph.D. in Pharmaceutical Science – Pharmaceutics and Drug Delivery
(Graduated, July 2012)

Thesis Title: *Multi-Compartmental Delivery Systems for Peptide and DNA Vaccines for Melanoma Immunotherapy*

Ms. Shanthi Ganesh Ph.D. in Pharmaceutical Science – Pharmaceutics and Drug Delivery
(Graduated, August 2012)

Thesis Title: *Hyaluronic Acid-Based Self-Assembled Multifunctional Nanosystems to Overcome Drug Resistance in Lung Cancer*

Ms. Lipa Shah Ph.D. in Pharmaceutical Science – Pharmaceutics and Drug Delivery
(Graduated, May 2013)

Thesis Title: *Multifunctional Nanoemulsions for Systemic Delivery of Analgesic Peptides to the CNS*

Ms. Jing Xu Ph.D. in Pharmaceutical Science - Interdisciplinary Option
(Graduated, June 2013)

Thesis Title: *Multimodal Therapeutic Strategy for Pancreatic Cancer: EGFR-targeted Gelatin-Based Nanovectors for Combination Wild-Type p53 Gene and Cytotoxic Drug Delivery*

Ms. Dipti Deshpande Ph.D. in Pharmaceutical Science – Pharmaceutics and Drug Delivery
(Graduated, July 2013)

Thesis Title: *Multimodal Omega-3 Fatty Acid Oil-Containing Nanoemulsion-Based Therapeutic Strategy for the Treatment of Endothelial Dysfunction in Coronary Artery Disease*

Ms. Aziza Jamal-Alial Ph.D. in Pharmaceutical Science - Interdisciplinary Option
(Graduated, August 2013)

Thesis Title: *Serum 25(OH)-Vitamin D Concentrations and Cardiovascular Disease Risk Associations among Older Puerto Ricans*

Mr. Shardool Jain Ph.D. in Pharmaceutical Science – Pharmaceutics and Drug Delivery
(Graduated, December 2013)

Thesis Title: *Macrophage-Targeted Tuftsin-Modified Non-Condensing Alginate Nanoparticles for Anti-Inflammatory Gene Therapy in Rheumatoid Arthritis*

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- Ms. Sunita Yadav
Delivery
Ph.D. in Pharmaceutical Science – Pharmaceutics and Drug
(Graduated, November 2014)
Thesis Title: *Intranasal Delivery of Peptide and siRNA Therapeutics Encapsulated in Lipid Nanocarriers to the Brain for the Treatment of Neuro-Inflammation*
- Ms. Verbena Kosvorasti
Delivery
Ph.D. in Pharmaceutical Science – Pharmaceutics and Drug
(Graduated, April, 2015)
Thesis Title: *Hyaluronic Acid Nanoparticles for Systemic RNA Interference Therapy of Advanced Sepsis*
- Ms. Ruchi Shah
Delivery
Ph.D. in Pharmaceutical Science – Pharmaceutics and Drug
Novartis/GSK Vaccines - Industrial Graduate Fellow
(Graduated, March 2016)
Thesis Title: *Evaluation and Optimization of Novel Self-Emulsifying Squalene Oil Emulsion Adjuvant Formulations for Potent Immune Response with Model Antigens*
- Mr. Husain Attarwala
Delivery
Ph.D. in Pharmaceutical Science – Pharmaceutics and Drug
(Graduated, March 2016)
Thesis Title: *Multi-Compartmental Oral Delivery Systems for TG-2 and IL-15 Gene Silencing in the Treatment of Celiac Disease*
- Ms. Ekta Kadakia
Delivery
Ph.D. in Pharmaceutical Science – Pharmaceutics and Drug
(Graduated, December, 2018)
Thesis Title: *Experimental Investigation and Mathematical Modeling for Nanoemulsion-Based Drug Delivery to the Central Nervous System*
- Mr. Rushit Lodaya
Delivery
PhD in Pharmaceutical Sciences – Pharmaceutics and Drug
GSK Vaccines - Industrial Graduate Fellow
(Graduated, June 2019)
Thesis Title: *Self-Emulsifying Adjuvant Systems Containing Alpha-Tocopherol for Subunit Vaccines*
- Ms. Dongyu Chen
Delivery
PhD in Pharmaceutical Sciences – Pharmaceutics and Drug
Dicerna Pharmaceuticals - Industrial Graduate Fellow
(Graduated, June 2019)
Thesis Title: *Role of Protein Corona on Tumor-Targeted Delivery of DsiRNA using Lipid Nanoparticles*
- Ms. Grishma Pawar
Delivery
PhD in Pharmaceutical Sciences – Pharmaceutics and Drug
(Graduated, June 2019)
-

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Mr. Dhaval Oza Ph.D. in Pharmaceutical Science – Pharmaceutics and Drug Delivery

Thesis Title: *Macrophage Reprogramming with microRNA Nanovectors in the Treatment of Metabolic Diseases*

Ms. Kanika Suri Ph.D. in Bioengineering

Thesis Title: *Oral Gene Therapy Targeting Macrophages in Intestinal Inflammatory Diseases*

Master's Students

Mr. Vijaykumar R. Patel M.S. in Biomedical Sciences – Pharmaceutics Specialization
(Graduated, September 1995).

Thesis Title: *Chitosan-Poly(Ethylene Oxide) Semi-Interpenetrating Polymer Network as a pH-Sensitive Drug Delivery System.*

Ms. Amira Ahmed M.S. in Biomedical Sciences – Pharmaceutics Specialization
(Graduated, September 1997).

Project Title: *Novel Drug Delivery Systems for the Treatment of H. pylori Infection.*

Ms. Sweta Shah M.S. in Biomedical Sciences – Pharmaceutics Specialization
(Graduated, September 1999).

Project Title: *Stomach-Specific Antibiotic Therapy for H. pylori Infection.*

Ms. Sarah Nsereko M.S. in Biomedical Sciences – Pharmaceutics Specialization
(Graduated, June 2001).

Thesis Title: *Chitin Microparticles for Localized Delivery of Paclitaxel: In Vitro and In Vivo Studies.*

Mr. Jugminder S. Chawla M.S. in Biomedical Sciences – Pharmaceutics Specialization
(Graduated, April 2002).

Thesis Title: *Poly(epsilon-caprolactone) Nanoparticles for Tumor-Targeted Delivery of Tamoxifen: In Vitro Studies.*

Mr. Ehab Taqieddin M.S. in Biomedical Sciences – Pharmaceutics Specialization
(Graduated, April 2002).

Thesis Title: *Enzyme Immobilization in Perm-selective Chitosan-Alginate Hybrid Microcapsules.*

Ms. Anupama Potineni M.S. in Biomedical Sciences – Pharmaceutics Specialization
(Graduated, April 2002).

Project Title: *Poly(Ethylene Oxide)-Modified Poly(Beta-Amino Ester) Nanoparticles: Long-Circulating pH Sensitive Biodegradable System for Paclitaxel Delivery.*

Mr. Srinivasan Namala M.S. in Biomedical Sciences – Pharmaceutics Specialization
(Graduated, June 2003).

Project Title: *Iontophoresis: A Tool to Enhance Transdermal Drug Delivery*

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Ms. Pallavi Devurkar M.S. in Biomedical Sciences – Pharmaceutics Specialization
(Graduated, June 2003).

Project Title: *In Vitro Evaluation of Chitosan Microspheres for Stomach-Specific Drug Delivery*

Ms. Lilian van Vlerken M.S. in Pharmaceutical Sciences – Pharmaceutics
Specialization
(Graduated, April 2005; Matriculated into the PhD program)

Project Title: *Combination Therapy of Ceramide and Paclitaxel Delivered in Poly(Ethylene Oxide)-Modified Poly(Epsilon-Caprolactone) Nanoparticles as a Potential Strategy for Overcoming Tumor Multidrug Resistance*

Mr. Gurinder S. Saini M.S. in Interdisciplinary Studies – Materials Science
Specialization
(Co-Advisor, under the Nanomedicine Consortium)
(Graduated, January 2006)

Thesis Title: *Preparation and Characterization of Superparamagnetic Iron Oxide-Gold Core-Shell Nanoparticles for Biomedical Applications*

Ms. Lipa Shah M.S. in Pharmaceutical Sciences – Pharmaceutics
Specialization
(Graduated, December 2006, Matriculated into the PhD program)

Thesis Title: *Biodegradable Polymeric Nanoparticles for Intracellular Saquinavir Delivery in HIV/AIDS*

Ms. Ankita Desai M.S. in Biotechnology – Pharmaceutical Science Track
(Graduated, December 2006)

Project Title: *In Vitro Evaluations of Multi-functional Nanoemulsion Formulations for Brain Tumor Therapy*

Ms. Jasneet Oberai M.S. in Pharmaceutical Sciences – Pharmaceutics
Specialization
(Graduated, May 2007)

Project Title: *Novel Nanoemulsions with Temperature-Responsive Drug Delivery*

Ms. Shraddha Babaria M.S. in Biotechnology – Pharmaceutical Science Track
(Graduated, August 2007)

Project Title: *Cationic Liposomes for Intranasal Gene Delivery to the Brain*

Ms. Sunita Yadav M.S. in Pharmaceutical Sciences – Pharmaceutics Specialization
(Graduated, December 2007, Matriculated into the PhD program)

Thesis Title: *Multifunctional Nanotherapeutic Strategy for MDR-1 Gene Silencing and Chemotherapy Administration to Overcome Multidrug Resistance in Cancer*

Ms. Dipti Deshpande M.S. in Pharmaceutical Sciences – Pharmaceutics
Specialization
(Graduated, December 2007, Matriculated into the PhD program)

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Thesis Title: *Biodegradable Nanoparticle System for Intracellular Administration of Paclitaxel and Ceramide in Coronary Restenosis*

Ms. Aparna Chavali M.S. in Biotechnology – Pharmaceutical Science Track
(Graduated, May 2008)

Project Title: *p53 Gene Therapy for Cancer*

Ms. Sunaina Pai M.S. in Pharmaceutical Sciences – Pharmaceutics Specialization
(Graduated, August 2008)

Thesis Title: *In Vitro Evaluations of Multifunctional Nanoparticles for Simultaneous EGFR Gene Silencing and Drug Delivery in Pancreatic Cancer*

Ms. Sindhura Ganga M.S. in Pharmaceutical Sciences – Pharmaceutics
Specialization
(Graduated, August 2008)

Thesis Title: *Multifunctional Nanoemulsion System for Combination Paclitaxel and Curcumin Delivery for Enhancement in Therapeutic Efficacy in Human Glioblastoma Cells*

Mr. Shardool Jain M.S. in Pharmaceutical Sciences – Pharmaceutics Specialization
(Graduated, August 2008; Matriculated into the PhD program)

Thesis Title: *Non-Condensing Calcium Alginate Microspheres for Gene Delivery and Transfection in Macrophages*

Ms. Padmaja Magadala M.S. in Pharmaceutical Sciences – Pharmaceutics Specialization
(Graduated, October 2008)

Project Title: *Epidermal Growth Factor Receptor-Targeted Gelatin-Based Nanovectors for Gene Therapy in Pancreatic Cancer Cells*

Ms. Pooja Sane M.S. in Pharmaceutical Sciences – Pharmaceutics Specialization
(Graduated, May 2009)

Project Title: *Down-Regulation of MDR-1 and MRP-1 by Curcumin Using Nanoemulsion Formulations in Drug Resistant Tumor Cells*

Ms. Saradha Chandrasekhar M.S. in Biotechnology – Pharmaceutical Science Track
(Graduated, May 2009)

Project Title: *DNA Delivery in Aortic Smooth Muscle and Endothelial Cells using Cationic Lipopolyplexes from Gelatin-Coated Stainless Steel Meshes*

Mr. Niraj Patel M.S. in Pharmaceutical Sciences – Pharmaceutics
Specialization
(Graduated, July 2009)

Thesis Title: *Targeted Methylene Blue-Containing Polymeric Nanoparticle Formulations for Oral Antimicrobial Photodynamic Therapy*

Mr. Chinmay Bakshi M.S. in Pharmaceutical Sciences – Pharmaceutics
Specialization

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(Graduated, July 2009)

Thesis Title: *Temperature-Sensitive Nanoemulsions made with Oils Rich in Polyunsaturated Fatty Acid in Enhancing Cytotoxicity and Apoptosis in Multidrug Resistant Tumor Cells*

Ms. Sandra Chadwick M.S. in Pharmaceutical Sciences – Pharmaceutics Specialization

(Graduated, August 2009)

Project Title: *Mucosal Delivery of Tuberculosis DNA Vaccination using Ovalbumin Nanoparticle-Containing W/O/W Multiple Emulsion-Based Hybrid Delivery System*

Ms. Anisha Korde M.S. in Pharmaceutical Sciences – Pharmaceutics Specialization
(Graduated, August 2010, Matriculated into the PhD program)

Project Title: *Stomach-Specific Chitosan-PEO Hydrogel Delivery Systems for H. pylori Infection*

Ms. Pei-Chin Tsai M.S. in Biotechnology – Pharmaceutical Science Track
(Graduated, December, 2010)

Project Title: *In Vitro Evaluations of EGFR-Targeted Gold-Coated Microspheres and Gold Nano-Rods for Imaging Oral Pre-cancerous Lesions*

Ms. Shruti Shah M.S. in Pharmaceutical Sciences – Pharmaceutics Specialization
(Graduated, December, 2010)

Thesis Title: *Hypoxia in Tumor Angiogenesis and Metastasis: Evaluation of VEGF and MMP Over-expression and Down-Regulation of HIF-1 α with RNAi in Hypoxic Tumor Cells*

Mr. Husain Attarwala M.S. in Pharmaceutical Sciences – Pharmaceutics Specialization

(Graduated, December, 2010, Matriculated into the PhD program)

Thesis Title: *In Vitro Evaluations of Macrophage-Targeted Anti-Inflammatory Gene Delivery and Transfection using Nanoparticle-in-Emulsion Formulations*

Mr. Milind Chalishazar M.S. in Pharmaceutical Sciences – Pharmaceutics Specialization

(Graduated, May, 2011)

Project Title: *Isolation and Evaluation of Human Melanoma Exosomes in Multiple Emulsion Formulation for Prophylactic and Therapeutic Vaccination*

Ms. Ruchi Shah M.S. in Pharmaceutical Sciences – Pharmaceutics Specialization

(Graduated, August, 2011, Matriculated into the PhD program)

Project Title: *Inhibition of Hypoxia-Inducible Factor-1 Activation in Pancreatic Tumor Spheroids with 2-Methoxyestradiol-Containing Polymeric Nanoparticles*

Mr. Hardip Gopani M.S. in Pharmaceutical Sciences – Pharmaceutics Specialization
(Graduated, August, 2011)

Thesis Title: *Combination Chemo- and Hyperoxia Therapy using Nanoemulsion Delivery Systems*

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Mr. Deep Shah M.S. in Pharmaceutical Sciences – Pharmaceutics Specialization
(Graduated, May, 2012)

Project Title: *Establishment and Characterization of an Adjuvant Arthritis Model in Lewis Rats*

Ms. Kinjal Sankhe M.S. in Pharmaceutical Sciences– Pharmaceutics Specialization
(Graduated, May, 2012)

Project Title: *In Vivo Evaluations of Endothelial Regenerative Effects of Estradiol-Encapsulated Nanoemulsions in Wild-type C57BL/6J and ApoE^{-/-} Knockout Mice*

Ms. Lavanya Thapa M.S. in Pharmaceutical Sciences – Pharmaceutics Specialization
(Graduated, May, 2012)

Project Title: *Evaluation of Melanoma Exosomes-Containing W/O/W Multiple Emulsion Vaccine Formulation in B16F10-Tumor Bearing C57BL6/J Mice*

Mr. Kamaljeet Singh Sandhu M.S. in Pharmaceutical Sciences – Pharmaceutics Specialization
(Graduated, August, 2012)

Project Title: *TNF- α Gene Silencing using Hyaluronic Acid-Based Self-Assembled Nanoparticles in Macrophages for the Treatment of Inflammatory Conditions Associated with Type 1 Diabetes*

Ms. Darshna Patel M.S. in Pharmaceutical Sciences – Pharmaceutics Specialization
(Graduated, August, 2012)

Thesis Title: *In Vitro Evaluations of Ceramide Co-Therapy in Non-Targeted and EGFR-Targeted Biodegradable Polymeric Nanoparticles for Enhancing Therapeutic Efficacy in Ovarian Cancer*

Ms. Sravani Kathireddy M.S. in Pharmaceutical Sciences – Pharmaceutics Specialization
(Graduated, May, 2013)

Project Title: *Multi-functional Nanoemulsions for Targeted Estradiol Delivery in the Treatment of Endothelial Dysfunction in Atherosclerosis*

Mr. Ganesan Venkatesan M.S. in Pharmaceutical Sciences – Pharmaceutics Specialization
(Graduated, May, 2013)

Project Title: *“Click” Synthesis and Characterization of Functionalized Hyaluronic Acid-Based Macrostructures for Self-Assembled Nanoparticles*

Ms. Ankita Raikar M.S. in Pharmaceutical Sciences – Pharmaceutics Specialization
(Graduated, August, 2013)

Thesis Title: *HIF-1 α Activation in 3D Tumor Spheroids and Evaluation of 2-Methoxyestradiol Therapy using Targeted Nanoparticle Formulations*

Mr. Aatman Doshi M.S. in Pharmaceutical Sciences – Pharmaceutics Specialization
(Graduated, August, 2013)

Thesis Title: *In Vitro Evaluations of Control and Lyp-1 Peptide-Modified Nano-Particulate Bisphosphonate Delivery for Ablation of Tumor-Associated Macrophages (TAMs)*

Page

Mr. Srujan Gandham M.S. in Pharmaceutical Sciences – Pharmaceutics Specialization

(Graduated, December 2014)

Thesis Title: *In Vitro Evaluations of Hexokinase-2 Inhibition with 2-Bromopyruvate Encapsulated in Targeted Nanocarrier Formulations using 3D Spheroid Models of Aerobic Glycolysis*

Mr. Adwait Oka M.S. in Pharmaceutical Sciences – Pharmaceutics Specialization
(Graduated, December 2014)

Thesis Title: *Targeted siRNA Delivery Strategy with Water-in-Oil-in-Water Multiple Emulsion for Modulation of Tumor-Associated Macrophage Polarity in Immunotherapy of Cancer*

Mr. Qijun (Oscar) Ouyang M.S. in Pharmaceutical Sciences – Pharmaceutics Specialization
(Graduated, May 2015)

Project Title: *Re-Polarization of Tumor Associated Macrophages with MicroRNA Nanovectors*

Ms. Grishma Pawar M.S. in Pharmaceutical Sciences – Pharmacology Specialization

(Graduated, May 2015 – Matriculated into the PhD program)

Project Title: *CNS Delivery of BDNF in Thermogelling Polymer Depot in Sprague-Dawley Rats*

Mr. Parin Shah M.S. in Pharmaceutical Sciences – Pharmacology Specialization

(Graduated, May 2015)

Project Title: *MicroRNA-Based Transfection and Epigenetic Changes in Lung Tumor Model*

Ms. Mei-Ju Su M.S. in Pharmaceutical Sciences – Pharmaceutics Specialization

(Graduated, December 2015).

Thesis Title: *Tumor Exosome-Mediated Macrophage Reprogramming in a Co-Culture Model and Evaluation of MicroRNA Delivery with Hyaluronic Acid-Based Nanoparticles*

Ms. Dandan Ling M.S. in Pharmaceutical Sciences – Pharmaceutics Specialization
(Graduated, May 2016).

Project Title: *miR-34a/Let-7a Combination Therapy in Refractory Lung Cancer using Targeted Hyaluronic Acid Nanoparticles*

Ms. Megha Suresh M.S. in Pharmaceutical Sciences – Pharmaceutics Specialization
(Graduated, May 2016).

Thesis Title: *Hetero-Cellular 3-D Spheroids of Pancreatic Tumor Cells for MicroRNA-34 Delivery using Hyaluronic Acid-Based Nanoparticles*

Page

Ms. Charul Avachat M.S. in Pharmaceutical Sciences – Pharmaceutics Specialization
(Graduated, December, 2017)

Thesis Title: *In Vitro Evaluations of BDNF Plasmid DNA Delivery and Transfection using Cationic Liposomes in Parkinson's Disease Model*

Ms. Krina Shah M.S. in Pharmaceutical Sciences – Pharmaceutics Specialization
(Graduated, December, 2017)

Thesis Title: *Pancreatic Tumor Cell-Fibroblast Heterocellular 3D Spheroid as a Model of Hypoxia and the Role of Nanoparticle-Mediated MicroRNA Therapy*

Ms. Samaher Osalian M.S. in Pharmaceutical Sciences – Pharmaceutics Specialization

Thesis Title: *Mitochondrial Network Density in Regulating Apoptosis and Neuronal Cell Death in Neurodegenerative Diseases*

Membership in Graduate Students Thesis Advisory Committees

Mr. Mukur Gupta	M.S. in Industrial Pharmacy, MA College of Pharmacy and Health Sciences (Graduated, June 2001). Ph.D. in Industrial Pharmacy, MA College of Pharmacy and Health Sciences (Graduated, February, 2004)
Mr. Anurag Singhal	M.S. in Pharmaceutics (Graduated, June 2002)
Ms. Prachi Parulkar (Graduated, August 2004)	M.S. in Pharmaceutics
Ms. Solani Bhardwaj (Graduated, December 2007)	M.S. in Chemical Engineering
Ms. Shweta Raini	M.S. in Pharmaceutics (Graduated, May 2009)
Ms. Aditi Jhaveri	M.S. in Pharmaceutics (Graduated, May 2009)
Mr. Kelton Barnsley	M.S. in Chemistry (Graduated, November 2014)
Ms. Roshani Patil	M.S. in Biomedical Engineering (Graduated, May 2019)
Mr. Jayesh Vora	Ph.D. in Pharmaceutics (Graduated, June 1994)
Ms. Kamelia Behnia	Ph.D. in Pharmaceutics (Graduated, September 1996)
Mr. Daniel J. Magiera, III	Ph.D. in Biomedical Sciences (Graduated, June 1997)
Ms. Sandhya Ramanathan	Ph.D. in Pharmaceutics (Graduated, September 1997)
Ms. Imran Vural	Ph.D. in Biomedical Sciences (Graduated, June 1998)
Ms. Sujata Vaidyanathan	Ph.D. in Pharmaceutics (Graduated, September 1998)
Mr. Ramin Darvari	Ph.D. in Pharmaceutics (Graduated, December 2001)
Mr. Ram Rammohan (Graduated, June 2002)	Ph.D. in Biomedical Sciences
Mr. Jose DaSilva	Ph.D. in Biomedical Sciences (Graduated, June 2002)
Mr. Ananth Srinivas Chakilam	Ph.D. in Pharmaceutics (Graduated, December 2004)
Mr. Sarathi Vijay Bodapatti	Ph.D. in Pharmaceutics (Graduated, August 2007)

Page

Ms. Suman Dandamudi (Graduated, January 2008)	Ph.D. in Pharmaceutics
Ms. Mattia Migliore	Ph.D. in Pharmacology/Nanomedicine (Graduated, May 2008)
Ms. Paula Lampton (Graduated, December 2008)	Ph.D. in Biology/Nanomedicine
Ms. Heather Brodtkin Chemistry/Nanomedicine (Graduated, May 2009)	Ph.D. in
Ms. D. Ece Gamsiz	Ph.D. in Chemical Engineering (Graduated, December 2009)
Mr. J. Adam Hendricks Chemistry/Nanomedicine (Graduated, December 2009)	Ph.D. in
Ms. Shifalika Tangutoori	Ph.D. in Pharmaceutics (Graduated, April 2010)
Ms. Tatyana Chernenko	Ph.D. in Chemistry/Nanomedicine (Graduated, April 2010)
Ms. Agnes Rafalko	Ph.D. in Chemistry/Nanomedicine (Graduated, May 2011)
Ms. Tao Wang December 2011)	Ph.D. in Pharmaceutics (Graduated,
Mr. Claudio Falcao	Ph.D. in Pharmaceutics (Graduated, December 2011)
Ms. Fulden Buyukozturk	Ph.D. in Chemical Engineering (Graduated, August 2012)
Mr. Robert Riehle	Ph.D. in Pharmaceutics/Nanomedicine (Graduated, May 2013)
Mr. Sean Essex	Ph.D. in Pharmaceutics (Graduated, August 2013)
Ms. Mary Katharine Balaconis	Ph.D. in Biomedical Engineering (Graduated, December 2013)
Ms. Jennifer Monahan-Fore (Graduated, December 2013)	Ph.D. in Chemistry/Nanomedicine
Mr. Michael Cuccarese	Ph.D. in Chemistry/Nanomedicine (Graduated, March 2014)
Ms. Jennifer Woodring (Graduated, December 2014)	Ph.D. in Chemistry/Nanomedicine
Mr. Helal Al-Suleimani	Ph.D. in Pharmaceutical Science (Graduated, December 2017)
Ms. Loraine Speciner	Ph.D. in Chemical Engineering (Graduated, March 2018)
Mr. Bumjun Kim	Ph.D. in Chemical Engineering (Graduated, November 2018)
Ms. Murui Han	Ph.D. in Pharmaceutical Science (Graduated, December 2018)
Ms. JuOae Chang	Ph.D. in Pharmaceutical Science (Graduated, May, 2019)
Ms. Wenjun De	Ph.D. in Pharmaceutical Science (Graduated, July 2019)
Ms. Archita Menon	Ph.D. in Pharmaceutical Sciences

Research Advising to Undergraduate Honors Students

Mr. Man-Hon (Johny) Lam (B.S., Class of 1994)
 Mr. Joseph M. Goreham (B.S., Class of 1995)
 Mr. Peter B. Ng (B.S., Class of 1995)
 Ms. Rakhee H. Tailor (B.S., Class of 1995)
 Ms. Mai-Ki Ly (B.S., Class of 1995)
 Mr. Ketankumar Patel (B.S., Class of 1996)
 Ms. Susanne Verrico (B.S., Class of 1996)
 Ms. Laurie Galvin (B.S., Class of 1996)
 Ms. Fiona Duncan (B.S., Class of 1997)
 Ms. Ekata V. Shah (Pharm.D., Class of 1997)
 - Recipient of Dean's Undergraduate Research Achievement Award, April 1995
 Ms. Rina Qaqish (Pharm.D., Class of 1997)
 Ms. Gity Roostai-Mills (B.S., Class of 1998)
 Ms. Roula Qaqish (Pharm.D., Class of 1998)

Page

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- Recipient of Dean's Undergraduate Research Achievement Award, April 1996
 - Currently Clinical Science Manager, Abbott Laboratories Eastern Division, Baltimore, MD
- Ms. Phung-Kim Lai (B.S., Class of 1999)
- Recipient of Dean's Undergraduate Research Achievement Award, April 1996
 - Recipient of the PhRMA Foundation's Undergraduate Research Fellowship, January 1999
- Ms. Tragiang Nguyen (B.S., Class of 1999)
- Ms. Trinh Tran (B.S., Class of 1999)
- Ms. Bich-Thuy Tran (B.S., Class of 1999)
- Mr. Chad McQueen (Pharm.D., Class of 2000)
- Recipient of Dean's Undergraduate Research Achievement Award, April 1999
- Ms. Angela L. Silvia (Pharm.D., Class of 2000)
- Recipient of Dean's Undergraduate Research Achievement Award, April 1999
- Mr. Kristian Jackson (B.S., Class of 2000)
- Recipient of the University of Connecticut Research Fellowship, June 1998
- Mr. Pulin Patel (B.S., Class of 2000)
- Pursued graduate studies in Pharmaceutical Chemistry at the University of Kansas, Lawrence, KS
- Mr. Derick Anderson (Pharm.D., Class of 2001)
- Recipient of Dean's Undergraduate Research Achievement Award, April 2000
- Ms. Kwai-Dzy Mak (Pharm.D., Class of 2001)
- Mr. Chi-Sing Nip (Pharm.D., Class of 2001)
- Recipient of the AAPS-AFPE "Gateway" Research Scholarship, June 2000
- Ms. Erica J. Waugh (Pharm.D., Class of 2002)
- Recipient of the PhRMA Foundation's Undergraduate Research Fellowship, January 2001
 - Recipient of Dean's Undergraduate Research Achievement Award, April 2002
- Ms. Nikita Mody (Pharm.D., Class of 2004)
- Recipient of Northeastern University Provost's Undergraduate Research Award, January 2002
 - Recipient of Dean's Undergraduate Research Achievement Award, April 2003
- Ms. Stephanie Whalen (Pharm.D., Class of 2006)
- Recipient of the AFPE "Gateway" Research Scholarship, June 2004
 - Recipient of Northeastern University Provost's Undergraduate Research Award, November 2004
- Ms. Sarah Rogers (Pharm.D., Class of 2008)
- Recipient of Northeastern University Provost's Undergraduate Research Award, November 2004
- Mr. Zeu Hong Tzeng (Pharm.D., Class of 2007)
- Recipient of the AFPE "Gateway" Research Scholarship, July 2005
 - Recipient of Northeastern University Provost's Undergraduate Research Award, January 2007
- Ms. Michelle Drown (Pharm.D., Class of 2009)
- Recipient of Northeastern University's Undergraduate Research Award, August 2005
- Ms. Erin Curran (Pharm.D., Class of 2007)
- Ms. Christina Guerra (Pharm.D., Class of 2012)
- Recipient of Northeastern University Provost's Undergraduate Research Award, September 2007
- Ms. Shubha Bhat (Pharm.D., Class of 2012)
- Mr. Ravi Patel (BS, Chemistry, Class of 2014)
- Ms. Erica Diamantides (Pharm.D., Class of 2015)
- Ms. Kristin Hong (Pharm.D., Class of 2015)
- Ms. Faryal Mir (BS, Biology/Pre-Med Program, Class of 2014)
- Ms. Kendall Donohoe (Pharm.D., Class of 2018)
-

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Ms. Rachael Heiss (Pharm.D., Class of 2019)
Ms. Sneha Hingorany (BS, Biology/Pre-Med Program, Class of 2019)
Ms. Reema Patel (Pharm.D., Class of 2020)
Ms. Mina Nayeri (Pharm.D., Class of 2019)
Ms. Priyanka Talagadadeevi (BS, Biomed Engr and Physics, Class of 2020)
Ms. Alyssa Bilotta (BS, Chemistry, Class of 2017)
Mr. Youngwoo Cho (Pharm.D., Class of 2020)
- Recipient of Northeastern University Provost's Undergraduate Research Award, September 2018
Ms. Casey Spellman (BS, Biochemistry, Class of 2020)
Ms. Alicia Sobeneau (BS, Molecular and Cell Biology, Class of 2022)
Ms. Suha Yacoob (BS, Chemical Engineering, Class of 2022)
Ms. Molly Haag (BS, Biochemistry, Class of 2022)

High School Summer Research Scholars

Ms. Phung-Kim Lai (Summer, 1994)
Ms. Luoisy Raymond (Summer, 1995)
Mr. Bao-Tuan Nguyen (Summer, 1995)
Mr. Kong-Jie Kah (Summer, 1997)
- Through Research Science Institute, Center for Excellence in Education, McLean, VA
Mr. Jeremy L. England (Summer, 1998)
- Research Science Institute, Center for Excellence in Education, McLean, VA
- Semi-Finalist in 1999 Intel High School Talent Search Competition
Ms. Iris Wei (Summer, 1999)
- Research Science Institute, Center for Excellence in Education, McLean, VA
- Semi-Finalist in the 2000 Intel High School Talent Search Competition
Mr. Brad M. Rosen (Summer, 2000)
- Research Science Institute, Center for Excellence in Education, McLean, VA
- Semi-Finalist in the 2001 Intel High School Talent Search Competition
Ms. Natalie Karabel (Summer, 2001)
- Research Science Institute, Center for Excellence in Education, McLean, VA
Ms. Feng Tu (Summer, 2002)
- Research Science Institute, Center for Excellence in Education, McLean, VA
- Semi-Finalist in the 2002 Siemens-Westinghouse High School Talent Search Competition
Ms. Maria Elena DeObaldia (Summer, 2003)
- Research Science Institute, Center for Excellence in Education, McLean, VA
- Winner of 2004 USA TODAY's All-USA High School Academic First Team
Ms. Joline Fan (Summer, 2004)
- Research Science Institute, Center for Excellence in Education, McLean, VA
- Finalist in the 2004 Siemens-Westinghouse High School Talent Search Competition
Mr. Harold Au (Summer, 2004)
- Research Science Institute, Center for Excellence in Education, McLean, VA
- Gold Award Winner at the 2005 Singapore Science and Engineering Fair.
- Award Winner at the 2005 Shanghai Science Expo, Shanghai, China.
Ms. Yi-Meng (Sally) Tan (Summer, 2005)
- Research Science Institute, Center for Excellence in Education, McLean, VA
- Semi-Finalist in the 2005 Siemens-Westinghouse High School Talent Search Competition
Ms. Thilini Ariyawansa (Summer, 2006)

Page

- Research Science Institute, Center for Excellence in Education, McLean, VA
- Winner of 2007 USA TODAY's All-USA High School Academic First Team

Ms. Elizabeth Lawler (Summer, 2006)

- Young Scholars Program, Center for STEM Education, Northeastern University, Boston, MA

Ms. Lili Ge (Summer, 2006)

- Young Scholars Program, Center for STEM Education, Northeastern University, Boston, MA

Ms. Ana Lyons (Summer, 2007)

- Research Science Institute, Center for Excellence in Education, McLean, VA

Mr. Zhi-Guang Ng (Summer, 2007)

- Research Science Institute, Center for Excellence in Education, McLean, VA

Ms. Jamie Kang (Summer, 2007)

- Young Scholars Program, Center for STEM Education, Northeastern University, Boston, MA

Ms. Marissa Dickson (Summer, 2007)

- Young Scholars Program, Center for STEM Education, Northeastern University, Boston, MA

Mr. Jia-Wei Lim (Summer, 2008)

- Research Science Institute, Center for Excellence in Education, McLean, VA

Mr. Mark-Alex Espanol (Summer, 2008)

- Young Scholars Program, Center for STEM Education, Northeastern University, Boston, MA

Ms. Rachael Le (Summer, 2008)

- Young Scholars Program, Center for STEM Education, Northeastern University, Boston, MA

Ms. Xiaojun Chen (Summer, 2009)

- Young Scholars Program, Center for STEM Education, Northeastern University, Boston, MA

Ms. Tien An (Summer, 2009)

- Young Scholars Program, Center for STEM Education, Northeastern University, Boston, MA

Mr. Gary Lee Lim (Summer, 2010)

- Research Science Institute, Center for Excellence in Education, McLean, VA

Ms. Manasi Malik (Summer, 2010)

- Young Scholars Program, Center for STEM Education, Northeastern University, Boston, MA

Ms. Fay Khudairi (Summer, 2010)

- Young Scholars Program, Center for STEM Education, Northeastern University, Boston, MA

Ms. Debra Van Egeren (Summer, 2011)

- Research Science Institute, Center for Excellence in Education, McLean, VA

Mr. Rahul Shankar (Summer, 2011)

- Research Science Institute, Center for Excellence in Education, McLean, VA

Ms. Kruti Vora (Summer, 2011)

- Young Scholars Program, Center for STEM Education, Northeastern University, Boston, MA

Ms. Jennifer Makovkina (Summer, 2011)

- Young Scholars Program, Center for STEM Education, Northeastern University, Boston, MA

Ms. Ruiyi Gao (Summer, 2012)

- Young Scholars Program, Center for STEM Education, Northeastern University, Boston, MA

Ms. Jennifer Flaherty (Summer, 2012)

- Young Scholars Program, Center for STEM Education, Northeastern University, Boston, MA

Mr. Nathan Kondamuri (Summer, 2012)

- Research Science Institute, Center for Excellence in Education, McLean, VA
-

Page

Ms. Minerva Tili (Summer, 2013)

- Young Scholars Program, Center for STEM Education, Northeastern University, Boston, MA

Mr. Juan Paniagua (Summer, 2013)

- Young Scholars Program, Center for STEM Education, Northeastern University, Boston, MA

Ms. Sejal Batra (Summer, 2013)

Mr. Rachit Singh (Summer, 2013)

- Research Science Institute, Center for Excellence in Education, McLean, VA

- Semi Finalist in the 2014 Intel Talent Search Competition

Ms. Batelhem Gemechu (Summer, 2014)

- Young Scholars Program, Center for STEM Education, Northeastern University, Boston, MA

Mr. Nathan Pan-Doh (Summer, 2014)

- Young Scholars Program, Center for STEM Education, Northeastern University, Boston, MA

Ms. Michelle Campeau (Summer, 2014)

- Research Science Institute, Center for Excellence in Education, McLean, VA

Mr. Ruchir Rastogi (Summer, 2014)

- Research Science Institute, Center for Excellence in Education, McLean, VA

- Semi Finalist in the 2014 Intel Talent Search Competition

Ms. Michelle Gee (Summer, 2015)

- Young Scholars Program, Center for STEM Education, Northeastern University, Boston, MA

Ms. Yasmeen Elaywan (Summer, 2015)

- Young Scholars Program, Center for STEM Education, Northeastern University, Boston, MA

Mr. Anirudh Jain (Summer, 2015)

- Research Science Institute, Center for Excellence in Education, McLean, VA

Mr. Yue (Jerry) Zhang (Summer, 2015)

- Research Science Institute, Center for Excellence in Education, McLean, VA

Ms. Caroline Quinn (Summer, 2016)

- Young Scholars Program, Center for STEM Education, Northeastern University, Boston, MA

Mr. Fred Eberstadt (Summer, 2016)

- Young Scholars Program, Center for STEM Education, Northeastern University, Boston, MA

Ms. Dina Shehata (Summer, 2016)

- Research Science Institute, Center for Excellence in Education, McLean, VA

Mr. Yilin (Alan) Huang (Summer, 2016)

- Research Science Institute, Center for Excellence in Education, McLean, VA

Ms. Sophia Luo (Summer, 2017)

- Research Science Institute, Center for Excellence in Education, McLean, VA

Mr. Timothy Tran (Summer, 2017)

- Research Science Institute, Center for Excellence in Education, McLean, VA

Ms. Junyi (Michelle) He (Summer, 2017)

- Young Scholars Program, Center for STEM Education, Northeastern University, Boston, MA

Ms. Sreenikitha (Nikki) Emani, (Summer, 2017)

- Young Scholars Program, Center for STEM Education, Northeastern University, Boston, MA

Mr. Hassan Osman (Summer, 2018)

- Research Science Institute, Center for Excellence in Education, McLean, VA

Mr. Yi-Yong Tan (Summer, 2018)

Page

1

- Research Science Institute, Center for Excellence in Education, McLean, VA

Mr. Dinesh Sangadi (Summer, 2018)

- Young Scholars Program, Center for STEM Education, Northeastern University, Boston, MA

Ms. Pamina Meija (Summer, 2018)

- Young Scholars Program, Center for STEM Education, Northeastern University, Boston, MA

Mr. Roc Bellostas (Summer, 2019)

- Research Science Institute, Center for Excellence in Education, McLean, VA

Mr. Edward Pham (Summer, 2019)

- Young Scholars Program, Center for STEM Education, Northeastern University, Boston, MA

Ms. Lauren Murphy (Summer, 2019)

- Young Scholars Program, Center for STEM Education, Northeastern University, Boston, MA

SERVICE

Professional

- Membership in Professional and Scientific Societies:

- American Association of Colleges of Pharmacy (1993-Present).

Member of the Council of Faculties.

Member of the Pharmaceutics SIG

Member of the Laboratory Instructors SIG

- American Association of Pharmaceutical Scientists (1987-Present).

Member of the Polymers in Drug Delivery SIG

Member of the Nanotechnology SIG

- The Controlled Release Society (1993-Present).

Scientific Advisory Board Member (2012-2014)

Member of Polymeric Biomaterial Discussion Group

- The Society for Biomaterials (1989-2010).

Member of the Task Force on the Impact of Biomaterials on Graduate Education.

Member of the Polymeric Materials Special Interest Group.

- Grant Reviewer:

- National Institutes of Health

National Heart, Lung, and Blood Diseases Institute (NHLBI) 2004 Program of Excellence in Nanotechnology – Special Emphasis Panel [ZHL1-CSR-K (F1)(R)].

Center for Scientific Review (CSR) November 2004 Gene and Drug Delivery (GDD) Study Section – SBIR/STTR Programs Special Emphasis Panel [ZRG1-BST-Z (10)].

National Institute of Allergy and Infectious Diseases (NIAID) 2005 Challenge Grants: Biodefense Product Development – Special Emphasis Panel [ZA11-TS-M (M5)(R)].

Center for Scientific Review (CSR) July 2005 Gene and Drug Delivery (GDD) Study Section Meeting – Temporary Member.

National Heart, Lung, and Blood Diseases Institute (NHLBI) October 2005 – Special Review Committee for P01 Program Proposals.

Center for Scientific Review (CSR), November 2005 Gene and Drug Delivery (GDD) Study Section – SBIR/STTR Programs Special Emphasis Panel [ZRG1 BST-Z 10(B)].

National Cancer Institute (NCI), March 2006 - Ruth L. Kirschstein NRSA Fellowships (F32/F33) in Cancer Nanotechnology Research (RFA-CA-06-010) Special Emphasis Panel [ZCA1 RTRB-Z(M1)(R)].

Center for Scientific Review (CSR), April, 2006 Gene and Drug Delivery (GDD) Study Section – SBIR/STTR Programs Special Emphasis Panel [ZRG1 BST-Z (10) (B)].

National Heart, Lung, and Blood Diseases Institute (NHLBI) May, 2006 – Special Review Committee for P01 Program Proposals.

Center for Scientific Review (CSR), June, 2006 – Special Emphasis Panel on Proposals in Response to RFA “Biology of RNA Interference” [2006/10 ZRG1 BST-Z (52) (R)].

Center for Scientific Review (CSR), March, 2007 – Special Emphasis Panel on Proposals in Response to RFA “Small Business: Orthopedics” [ZRG1 MOSS (10)].

Center for Scientific Review (CSR), July, 2007 – Cancer Drug Development and Therapeutics SBIR/STTR ONC-V (13) [2007/10 ZRG1 ONC-V (13) B].

Center for Scientific Review (CSR), October 2007 – ZRG1 NANO-M (01) “Nanotechnology” Study Section – Temporary Member.

National Institute of Biomedical Engineering and Bioimaging (NIBIB), July 2008 - ZEB1 OSR-E (O1) S “Special Emphasis Panel/Scientific Review Group 2008/10 on T32/K99/K01 Training Grants”.

National Institute of General Medical Sciences (NIGMS), August 2008 2008/10 ZGM1 MBRS-0 (NP) “Support of Competitive Research (SCORE) Minority Biomedical Research Support in Neurophysics” Special Emphasis Panel.

National Cancer Institute (NCI), October, 2008, 2009/01 ZRG1 ONC-X (14) B “Experimental Cancer Therapeutics SBIR/STTR” Special Emphasis Panel.

National Institute of Biomedical Imaging and Bioengineering (NIBIB) Special Emphasis Panel. 2009/01 ZEB1 OSR-B (J1) S. November 2008 Support for Scientific Conference (R13) Grant Application Review Panel.

Center for Scientific Review (CSR), January, 2009 – Cancer Immunopathology and Immunotherapy Study Section (CII), *Ad Hoc* Reviewer.

Center for Scientific Review (CSR), April, 2009 – 2009/05 ZRG1 BST-G (10) B - Assays, Detectors, and Devices SBIR/STTR Panel, *Ad Hoc* Reviewer.

Center for Scientific Review (CSR), June 2009 - 2009/10 ZRG1 BST-M (58) R, RFA OD-09-003 Challenge Grants Panel 4, *Ad Hoc* Reviewer.

National Cancer Institute (NCI), July 2009, 2009/01 ZRG1 OTC-X 14 B, Experimental Cancer Therapeutics, SBIR Special Emphasis Panel.

Center for Scientific Review (CSR), October, 2009, 2010/01 BTSS Bioengineering Technology and Surgical Sciences Study Section. *Ad Hoc* Reviewer.

Center for Scientific Review (CSR), February, 2010, 2010/05 BTSS Bioengineering Technology and Surgical Sciences Study Section. *Ad Hoc* Reviewer.

National Cancer Institute (NCI), June 2010 ZCA1 SRLB-Q C1 B, Multifunctional Therapeutics Phase II Special Emphasis Panel, Reviewer.

National Institute of Drugs of Abuse (NIDA), July, 2010 ZDA1 JXR-D (10) Special Emphasis Panel, Reviewer.

Center for Scientific Review (CSR), September 2010, 2011/01 ZRG1 BST-N (03) Member Conflicts: Bioengineering Sciences and Technologies, *Ad Hoc* Reviewer.

Center for Scientific Review (CSR), September 2010, 2011/01 ZRG1 IMST-K (03) Member Conflict: Enabling Bioanalytical and Imaging Technologies, *Ad Hoc* Reviewer.

Center for Scientific Review (CSR), February, 2011, 2011/01 BTSS Bioengineering Technology and Surgical Sciences Study Section. *Ad Hoc* Reviewer.

Center for Scientific Review (CSR), September, 2011, 2011/01 BTSS Bioengineering Technology and Surgical Sciences Study Section. *Permanent Member*.

Center for Scientific Review (CSR), May, 2012, 2012/10 PAR11-301-303: Pediatric Drug Formulations and Drug Delivery (ZRG1 ETTN-S (50) R) Special Emphasis Panel, *Co-Chair*.

National Institute of Biomedical Imaging and Bioengineering (NIBIB), July 2013, 2013/10 ZEB1 OSR-E (O1) S. NIBIB K Training Meeting (Teleconference) Special Emphasis Panel, *Member*.

Center for Scientific Review (CSR), June, 2016 and Feb, 2017 – Cancer Immunopathology and Immunotherapy Study Section (CII), *Ad Hoc* Reviewer.

- Department of Defense, United States Army Medical Research and Material Command, Congressionally-

Directed Medical Research Program

Breast Cancer Research Program Review Panel (2006-Present)

Breast Cancer Concept Award Review Panel (2010-Present)

Breast Cancer Training Program Review Panel (2010-2012)

Peer Reviewed Medical Research Program – Pre-applications for Inflammatory Bowel Disease-1 (2013)

- United States Department of Agriculture

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Investigator Initiated Proposals.
SBIR/STTR Proposals.

- United States Food and Drug Administration
Intramural Proposals on Nanotechnology
- American Chemical Society, Washington, DC
Petroleum Research Funds
- Susan G. Komen Foundation for Breast Cancer Grant Program, Dallas, TX
- American Association for Advancement of Science, Life Sciences Discovery Fund,

Washington, DC

- Georgia Cancer Coalition Grant Program, Atlanta, GA
- University of Missouri Intramural Grant Program, Columbia, MO
- University of Kansas Intramural Grant Program, Lawrence, KS
- Medical Research Council of United Kingdom, London, UK
- The Wellcome Trust of United Kingdom, London, UK
- The Leenaards Foundation Prize, Lausanne, Switzerland
- The Netherlands Organisation for Scientific Research – The Netherlands
- National Medical Research Council, Ministry of Health, Singapore
- Singapore Science and Engineering Research Council (SERC) – an Agency of Science, Technology and Research Singapore (A*STAR), Singapore City
- Israel Science Foundation, Tel Aviv, Israel
- Czech Science Foundation, Prague, Czech Republic
- Hong Kong Innovation and Technology Support Programme, Wanchai, Hong Kong
- Hong Kong Research Grants Council, Wanchai, Hong Kong
- Skolkovo Foundation, Moscow, Russia
- Danish Research Council, Copenhagen, Denmark
- Kuwait Foundation for the Advancement of Science, Kuwait City, Kuwait
- Omani Research Council, Muscat, Oman
- South African Medical Research Council, Durban, South Africa
- Scientific Foundation of Ireland, Dublin, Ireland

- Membership in Industrial and Academic Scientific Advisory Boards:
 - Bessor Pharma, Inc., Framingham, MA (Scientific Advisory Board member)
 - Targagenix, Inc., Stony Brook, NY (Scientific Advisory Board member)
 - Nemucore Medical Innovations, Wellesley, MA (Founder and Scientific Advisory Board member)
 - Blue Ocean Biomanufacturing, Inc., Worcester, MA (Founder and Scientific Advisory Board member)

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- OnSite Therapeutics, Inc., Lowell, MA (Scientific Advisory Board member)
 - Cerulean Pharmaceuticals, Inc., Cambridge, MA (Scientific Advisory Board member)
 - Aten Porus Life Sciences Private, LTD, Bangalore, India (Scientific Advisory Board member)
 - Controlled Release Society (Scientific Advisory Board member)
 - Center for Nanomedicine and Drug Delivery, Xavier University of Louisiana, New Orleans, LA (Scientific Advisor)
 - International Symposium on Recent Advances in Drug Delivery Systems, University of Utah, Salt Lake City, UT (Scientific Advisor)

 - Journal Editorships:
 - Editor for America, *Drug Delivery and Translational Research*
 - Associate Editor, *Open Nano*
 - Associate Editor, *International Journal of Green Nanotechnology: Biomedicine*
 - Associate Editor, *Nanomedicine: Nanotechnology, Biology, and Medicine* (2008-2015)

 - Membership in Journal Editorial Boards:
 - Journal of Controlled Release
 - Drug Design, Development and Therapy
 - Expert Opinion on Drug Delivery
 - Journal of Biopharmaceutics and Biotechnology
 - Journal of Nano Education
 - Nanotechnology, Science and Applications
 - Pharmaceutical Formulations and Quality
 - Recent Patents on Drug Delivery and Formulations
 - Synthesis and Reactivity in Inorganic, Metal-Organic, and Nano-Metal Chemistry
 - Tissue Barriers
 - The Open Drug Delivery Journal

 - Reviewer for Scientific Journals (partial list):
 - ACS Nano
 - Advanced Drug Delivery Reviews
 - Angewandte Chemie, International Edition
 - Bioconjugate Chemistry
 - Biomacromolecules
 - Biomaterials
 - Cancer Chemotherapy and Pharmacology
 - Cancer Letters
 - Cancer Research
 - Carbohydrate Polymers
 - European Polymer Journal
 - European Journal of Pharmaceutics and Biopharmaceutics
 - European Journal of Pharmaceutical Sciences
 - Expert Opinion on Drug Delivery
 - Expert Opinion on Biological Therapy
 - Gene Therapy
 - International Journal of Cancer
 - International Journal of Pharmaceutics
 - Journal of Applied Polymer Sciences
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- Journal of the American Chemical Society
 - Journal of Biomaterial Science, Polymer Edition
 - Journal of Biomedical Materials Research
 - Journal of Controlled Release
 - Journal of Liposome Research
 - Journal of Pharmacy and Pharmacology
 - Journal of Pharmaceutical Sciences
 - Journal of Pharmacology and Experimental Therapeutics
 - Life Sciences
 - Macromolecular Biosciences
 - Molecular Cancer Therapeutics
 - Molecular Pharmaceutics
 - Nature Communications
 - Nature Nanotechnology
 - Nature Reviews Drug Discovery
 - Pharmaceutical Research
 - Polymer International
 - Science
 - Science Advances
 - Science Translational Medicine
 - Small
 - STP Pharma Sciences
- Participation in Short Courses:
- Scanning Probe Microscopy Seminar and Workshop. Woburn, MA.
 - Particle Technology Seminar and Workshop. Natick, MA.
 - Application of HTML for Developing Instructional Materials. Boston, MA.
 - Absolute Macromolecular Characterization with Light Scattering. Boston, MA.
 - Scientific and Engineering Applications of Macintosh® Computers. Boston, MA.
 - Surface Characterization of Biomedical Materials. Phoenix, AZ.
 - Hydrogels in Medicine and Pharmacy. Indianapolis, IN.
- American Association of Pharmaceutical Scientists (AAPS), Northeast Regional Discussion Group
Planning Committee Member (2001-2005).
- Organizer of the National Cancer Institute/Nano Science and Technology Institute Special Symposium on *"Nanotechnology for Cancer Prevention, Diagnosis, and Treatment"* (2005-Present).
- Instructor for Nano Science and Technology Institute's Tutorial Session on *"Nanotechnology for Medical Imaging and Therapy"* (2005 – Present).
- Scientific Organizing Committee Member and Session Chair of the *"Cancer Nanotech Conference: Detecting and Treating Cancer"*. Paris, France. (2005-2007).
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- Organizer of the “2009 Indo-US Cancer Nanotechnology Symposium”, sponsored by the Indo-US Science and Technology Forum, New Delhi, India. February 2009.
- Organizer of the Materials Research Society, Spring 2012 Meeting, San Francisco, CA. Symposium on “Nanomedicine for Molecular Imaging and Therapy” March, 2012.
- Registered Pharmacist in MA since 1988 (license #: 20415).

University, College, School, & Department

- Faculty Delegate to the United States Pharmacopeia (USP) Convention (2003-Present).
- Faculty Advisor – American Association of Pharmaceutical Scientist – Northeastern University Student Chapter (2009-2015)
- Faculty Advisor - Beta Tau Chapter, Rho Chi Pharmaceutical Honor Society (1993-1999).
- Coordinator of the American Association of Pharmaceutical Scientists, Visiting Scientist Program (1993-1999).
- Presentations for Pharmacy Continuing Education Programs.
 - *Helicobacter pylori* and Peptic Ulcer Disease
 - Advances in Drug Delivery Systems: A Primer for Pharmacists
 - Nanomedicine: Realizing the Potential of Targeted and Molecular Therapies
 - Pharmaceutical Calculations: A Primer for Pharmacists and Pharmacy Technicians
- Participation in Pharmacy Open Houses and Student Orientations.
- Participation in Pharmacy Alumni Activities.
- Pharmacy Student’s Academic Advising/Portfolio Reviewer.
- Committee Assignments:

University:

- University Distinguished Professorship Committee (2016-Present)
 - University Patent Committee (2002-2009, 2012-Present).
 - Biotechnology Academic Steering Committee (2002-Present).
 - Senate Search Committee for Bouve College Dean (2011-2012).
 - Provost’s Tenure Advisory Committee (2008-2010).
 - Academic Computing Advisory Committee (2004-2006).
 - Senate Library Advisory Committee (2001-2007).
 - Education Technology Faculty Advisory Committee (2004-2006)
 - Senate Committee for Evaluation of Dean of Nursing (2004-2006).
 - Senate Committee for Evaluation of Dean of Libraries (2003-2004).
 - Executive Committee of the Biotechnology Initiative (2002-2004).
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- Senate Committee for Department of Pharm. Practice Chair Search (2001-2002).
- University Instructional Technology Task Force (2000-2001).
- Senate Committee for Department of Pharm. Sciences Chair Search (1996-1997).

Bouvé College:

- Bouve Dean's Leadership Team (2011-2016).
- Bouve Administrative Committee (2005 – 2011).
- Associate Dean for Research Search Committee (2010-2011).
- George D. Behrakis Endowed Professor Search Committee (2002-2004).
- College Technology Committee (1998-2000).
- College Diversity Committee, (1994-1995).
- College Computer Advisory Committee, (1995-1998).
- Graduate Education and Research Task Force (1998-1999).
- Graduate Committee for Biomedical Sciences Program (1998-2000).

School of Pharmacy:

- Pharmacy Executive Committee (2008-Present).
- Pharmacy Steering Committee (2001-2004, 2005-Present).
- Pharmacy Curriculum Committee (1998-2002, 2007-Present).
- Pharmacy Re-Accreditation/Self-Study Committee, (1995-1996, 2008-2010).
- Pharmacy Professional Affairs Committee (2006-2009)
- Pharmacy Transfer Students Admission Committee, (1994-2001, 2003-2007).
- Graduate Committee of the School of Pharmacy (2002-2006).
- Pharmacy Honors and Awards Committee, (1994-2001).
- Pharmacy Progression Requirements Committee, (1996-2000).
- Pharmacy Laboratory Renovation Committee (1997-1999).
- Doctor of Pharmacy Tracking Admission Committee (1998-2000).
- Doctor of Pharmacy Curriculum Working Group (1996-1999)*.

Departmental of Pharmaceutical Sciences:

- Merit Review Committee, (1994-1996, 1997-2000, 2002-2003, 2007-2008).
- Faculty Search Committees, (1994-1996, 1998-1999, 2002-2003*, 2007-2008).
- Pharmaceutical Sciences Workload Policy Committee (2005-2007*)
- BS in Pharm. Sciences Program Evaluation Committee (2001-2003, 2009-2010).

* *Committee Chair*

Community

- Discuss Pharmacy as a Career Choice to Middle and High School Students and Parents.
- Provide Math and Science Tutoring to Middle and High School Students.
- Participate in Fund Raising Activities for Local Schools and Charitable Community Organizations

AWARDS AND HONORS

- Purdue University, College of Pharmacy, Distinguished Alumni Award – 2019.
- Web of Science Highly Cited Author (Top 1%) in Pharmacology & Toxicology – 2015 & 2019.
- Northeastern University, School of Pharmacy Distinguished Alumni Award – 2016.
- Northeastern University, University Distinguished Professorship Award – 2016.

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- Controlled Release Society – Induction into the College of Fellows – 2014.
 - Phi Lambda Sigma, Pharmacy Leadership Society, Honorary Member – 2014.
 - Controlled Release Society - Tsuneji Nagai Award – 2012.
 - American Association of Pharmaceutical Scientists (AAPS) Fellowship, 2007.
 - American Association of Pharmaceutical Scientists (AAPS) - Meritorious Manuscript Award, 2007.
 - Nano Science and Technology Institute (NSTI) Fellowship Award for Outstanding Contributions towards the Advancement, in Nanotechnology, Microtechnology, and Biotechnology, 2006.
 - Cited in Academic Pharmaceutical Scientists Who's Who, 2004.
 - Eurand Award for Outstanding Research in Oral Drug Delivery, Third Prize, 2003.
 - Special Faculty Recognition Award from the Doctor of Pharmacy Students, Class of 1999.
 - Recipient of Rho Chi Advisor Appreciation Award, 1997, 1998, & 1999.
 - Recipient of Dean's Excellence in Teaching Award, 1996.
 - Cited in Who's Who in Science and Engineering, 1996.
 - Member of Sigma Xi - The Scientific Research Society, 1996.
 - Member of Rho Chi - Pharmaceutical Honor Society, 1987.
 - Recipient of Dean's Undergraduate Research Achievement Award, 1987.
 - Recipient of Burroughs Wellcome Academic Scholarship, 1987.
 - Recipient of Dean Leroy Keagle Memorial Scholarship, 1986.

Last Updated: November 2019

Attachment B

Leonard J. Chyall, Ph.D.

Education

B.A. (Chemistry), 1986, Oberlin College, Oberlin, OH

Ph.D. (Chemistry), 1991, University of Minnesota, Minneapolis, MN

Postdoctoral Fellow, 1992-1996, Purdue University, West Lafayette, IN

Pharmaceutical Solids and Regulatory Affairs Short Course, Purdue University, 2001

Employment

**May 2011 – Chyall Pharmaceutical Consulting, LLC; West Lafayette, Indiana
President and Consultant**

Independent consultant serving the pharmaceutical industry. Expertise in synthetic chemistry, and analytical testing of drug substances and drug products. Services directed toward scientific data and document review, laboratory testing, and technical assistance with IP matters.

**2000-2011 Aptuit, Inc. (formerly SSCI, Inc.), West Lafayette, Indiana
Director (August 2010 – May 2011)
Principal (January 2007 – July 2010)
Senior Research Investigator (2003 - 2006)
Research Investigator (2000 - 2003)**

Project manager and group leader for external client projects involving various aspects of organic and analytical chemistry. These projects involve the development of new products (primarily pharmaceuticals) or providing scientific consulting to support patent litigation, counterfeit analysis or tampering analysis projects. Leader of a department responsible for fee-for-service laboratory testing and consulting services. Responsible for business development, client relations, and strategic planning of the business. Administrative supervisor for numerous chemists throughout my tenure with the organization.

**1996-2000 Great Lakes Chemical (now Chemtura), West Lafayette, Indiana
Research Chemist**

Lead Scientist for a new technology development program in the GLCC Corporate R&D division. Technology Coordinator for contract research programs. Project Leader for a new product development project in GLCC Polymer Additives R&D.

Representative Technical Skills

Analytical Chemistry

- Mass Spectrometry
 - Triple Quadrupole Systems
 - Ion Cyclotron Resonance MS
 - Ion-Molecule Chemistry
- Chromatography (HPLC, MPLC, TLC and preparative chromatography)
- Infrared (IR) and Raman Spectrometry
- NMR spectroscopy
- Spectrophotometry
- Solubility and dissolution testing
 - USP dissolution testing
 - Intrinsic dissolution rate studies
- Powder dissolution testing
- pH measurements
- Potentiometric titrations
- Karl Fischer titration

Organic Chemistry

- Synthetic chemistry
 - mg to kg scale laboratory reactions
 - high pressure reactions
 - air-sensitive procedures
- Crystallization methods
- Enantiomer resolutions
- Polymorph, salt and cocrystal screening and characterization

Solid Form Analytical Techniques

- X-ray powder diffraction (XRPD)
- Thermogravimetric analyses (TGA)
- Differential scanning calorimetry (DSC)
- Optical microscopy
- Moisture sorption/desorption analyses

Professional Affiliations and Activities

- American Chemical Society
- American Association of Pharmaceutical Scientists
- Purdue Research Park Life Sciences Executive Council
- Guest Lecturer, Chemistry Department, Purdue University (Undergraduate Organic Chemistry Courses) 2016 – 2017.

Publications

1. Chyall, L. J. Current Applications of X-Ray Powder Diffraction in the Pharmaceutical Industry *Am. Pharm. Rev.* **2012**, *15*, 70-73.
2. Park, A.; Chyall, L.; Dunlap, J.; Schertz, C.; Jonaitis, D.; Stahly, B.; Bates, S.; Shipplett, R.; Childs S. New solid-state chemistry technologies to bring better drugs to market: knowledge-based decision making. *Exp. Opin. Drug Disc.*, **2007**, *2(1)*, 145-154.
3. Lohani, S.; Zhang, Y.; Chyall, L. J.; Mougin-Andres, P.; Muller, F. X.; Grant, D. J. W. Carbamazepine-2,2,2-trifluoroethanol (1/1). *Acta Cryst.* **2005**, *E61*, 1310-1312.
4. Childs, S. L.; Chyall L. J.; Dunlap, J. T.; Smolenskaya, V. N.; Stahly B. C.; Stahly, G. P. Crystal Engineering Approach to Forming Cocrystals of Amine Hydrochlorides with Organic Acids. Molecular Complexes of Fluoxetine Hydrochloride with Benzoic, Succinic, and Fumaric Acids. *J. Am. Chem. Soc.* **2004**, *126*, 13335-13342.

5. Childs, S. L.; Chyall, L. J.; Dunlap, J. T.; Coates, D. A.; Stahly, B. C.; Stahly, G. P. A Metastable Polymorph of Metformin Hydrochloride: Isolation and Characterization Using Capillary Crystallization and Thermal Microscopy Techniques. *Crystal Growth & Design* **2004**, *4*, 441-449.
6. Chyall, L. J.; Tower, J. M.; Coates, D. A.; Houston, T. L.; Childs, S. L. Polymorph Generation in Capillary Spaces: The Preparation and Structural Analysis of a Metastable Polymorph of Nabumetone. *Crystal Growth & Design* **2002**, *2*, 505-510.
7. Morgan, A. B.; Harris, R. H., Jr.; Kashiwagi, T.; Chyall, L. J.; Gilman, J. W. Flammability of polystyrene layered silicate (clay) nanocomposites: Carbonaceous char formation. *Fire and Materials* **2002**, *26*, 247-253.
8. Hill, B. T.; Poutsma, J. C.; Chyall, L. J.; Hu, J.; Squires, R. R. Distonic ions of the "Ate" class. *J. Am. Soc. Mass Spectrom.* **1999**, *10*(9), 896-906.
9. Gassman, P. G.; Han, S.; Chyall, L. J. Thermal rearrangement of trans-7,7-dihalobicyclo[4.1.0]hept-3-enes. *Tetrahedron Lett.* **1998**, *39*(31), 5459-5462.
10. Poutsma, J. C.; Seburg, R. A.; Chyall, L. J.; Sunderlin, L. S.; Hill, B. T.; Hu, J.; Squires, R. R. Combining Electrospray Ionization and the Flowing Afterglow Method. *Rapid Commun. Mass Spectrom.* **1997**, *11*, 489-493.
11. Chyall, L. J.; Squires, R. R. The Proton Affinity and Absolute Heat of Formation of Trifluoromethanol. *J. Phys. Chem.* **1996**, *100*, 16435-16440.
12. Leeck, D. T.; Li, R.; Chyall, L. J.; Kenttämä, H. I. Homolytic Se-H Bond Energy and Ionization Energy of Benzeneselenol, and the Acidity of the Corresponding Radical Cation. *J. Phys. Chem.* **1996**, *100*, 6608-6611.
13. Chyall, L. J.; Squires, R. R. Determination of the proton affinity and absolute heat of formation of cyclopropenylidene. *Int. J. Mass Spectrom. Ion Processes* **1995**, *149/150*, 257-266.
14. Smith, R. L.; Chyall, L. J.; Beasley, B. J.; Kenttämä, H. I. The Site of Protonation of Aniline. *J. Am. Chem. Soc.* **1995**, *117*, 7971-7973.
15. Chou, P. K.; Smith, R. L.; Chyall, L. J.; Kenttämä, H. I. Reactivity of the Prototype Organosulfur Distonic Ion: $\bullet\text{CH}_2\text{SH}_2^+$. *J. Am. Chem. Soc.* **1995**, *117*, 4374-4378.
16. Chyall, L. J.; Kenttämä, H. I. Gas-phase reactions of the 4-dehydroanilinium ion and its isomers. *J. Mass Spectrom.* **1995**, *30*, 81-87.
17. Chyall, L. J.; Byrd, M. H. C.; Kenttämä, H. I. Reactions of the Charged Radical $(\text{CH}_3)_2\text{S}^+-\text{CH}_2\bullet$ with Cyclic Alkenes. *J. Am. Chem. Soc.* **1994**, *116*, 10767-10772.
18. Chyall, L. J.; Brickhouse, M. D.; Schnute, M. E.; Squires, R. R. Kinetic versus Thermodynamic Control in the Deprotonation of Unsymmetrical Ketones in the Gas Phase. *J. Am. Chem. Soc.* **1994**, *116*, 8681-8690.
19. Chyall, L. J.; Kenttämä, H. I. The 4-Dehydroanilinium Ion: a Stable Distonic Isomer of Ionized Aniline. *J. Am. Chem. Soc.* **1994**, *116*, 3135-3136.

20. Smith, R. L.; Chyall, L. J.; Stirk, K. M.; Kenttämä, H. I. Radical-type reactivity of the methylenedimethylsulfonium ion, $(\text{CH}_3)_2\text{S}^+-\text{CH}_2^\bullet$ *Org. Mass Spectrom.* **1993**, 28, 1623-1631.
21. Smith, R. L.; Chyall, L. J.; Chou, P. K.; Kenttämä, H. I. The Acyclic Distonic Isomer of Ionized Cyclopentanone: $^\bullet\text{CH}_2\text{CH}_2\text{CH}_2\text{CH}_2\text{CO}^+$ *J. Am. Chem. Soc.* **1994**, 116, 781-782.
22. Mlinaric-Majerski, K.; Vinkovic, V.; Chyall, L. J.; Gassman, P. G. Deuterium isotope effects on nuclear shielding. Cross-ring effects in rigid cyclic molecules. *Magn. Reson. Chem.* **1993**, 31, 903-905.
23. Brickhouse, M. D.; Chyall, L. J.; Sunderlin, L. S.; Squires, R. R. Kinetics of isobaric ion/molecule reactions determined by the flowing afterglow-triple quadrupole technique. *Rapid Commun. Mass Spectrom.* **1993**, 7, 383-3

Patents

1. Gushurst, K. S.; Chyall, L. J.; Koztecki, L. H.; Wolfe, B. S. Crystalline forms of oxymorphone hydrochloride US 8,563,571 (October 22, 2013).
2. Quigley, K. A.; Still, E. J.; Chyall, L. J. 4-[3[(4-Cyclopropanecarbonyl)-piperazine-1-carbonyl]-4-fluorobenzyl]-2H-phthalazin-1-one. US 8,183,369 B2 (May 22, 2012).
3. Chyall, L. J.; Hodgen, H. A.; Vyverberg, F. J.; Chapman, R. W. Intumescent Polymer Compositions. US 6,905,693 (June 14, 2005).
4. Chyall, L. J.; Hodgen, H. A.; Vyverberg, F. J.; Chapman, R. W.; Chou, P. K. Intumescent Polymer Compositions. US 6,632,442 B1 (October 14, 2003).
5. Robin, M. L.; Mazac, C. J.; Chyall, L. J.; Kleindl, P. Bromine-containing 1,2-bis(phenyl)difluoromethanes and method of imparting flame retardancy to flammable materials. US 6,348,633 (February 19, 2002).

Papers Presented

1. "Crystallization Studies of Nabumetone: Preparation and Characterization of a Novel, High-Energy Polymorph." Chyall, L. J.; Tower, J. M.; Coates, D. A.; Houston, T. L., 223rd National Meeting of the American Chemical Society, Orlando, FL, April 7-11, 2002: Abstract IEC 268
2. "The Synthesis and Properties of 7,7-Dichloro-*trans*-bicyclo-[4.1.0]-hept-3-ene." P. G. Gassman and L. J. Chyall, 22nd Great Lakes Regional Meeting of the American Chemical Society, Duluth, MN, May 31-June 2, 1989: Abstract 98.
3. "The Synthesis and Thermal Isomerization of 7,7-Dihalo-*trans*-bicyclo-[4.1.0]-hept-3-enes." P. G. Gassman and L. J. Chyall, 201st National Meeting of the American Chemical Society, Atlanta, GA, April 14-19, 1991: Abstract ORGN 228.

4. "Free Radical Rearrangements of Dihalo-*trans*-bicyclo-[4.1.0]-hept-3-enes." P. G. Gassman and L. J. Chyall, 32nd National Organic Chemistry Symposium, University of Minnesota, Minneapolis, MN, June 16-20, 1991: Abstract B-65.
5. "Kinetic Versus Equilibrium Control in the Deprotonation of Unsymmetrical Ketones in the Gas Phase." L. J. Chyall, M. D. Brickhouse, M. E. Schnute, and R. R. Squires, 205th National Meeting of the American Chemical Society, Denver, CO, March 28-April 2, 1993: Abstract ORGN 29.
6. "Ion-Molecule Chemistry of the Methylene Dimethylsulfonium Ion: A Novel Alpha-Distonic Ion." L. J. Chyall, R. L. Smith, K. M. Stirk, and H. I. Kenttämä, 41st ASMS Conference on Mass Spectrometry, San Francisco, CA, May 30-June 4, 1993: Abstract MOD 12:10
7. "Radical-Type Reactivity of Distonic Ions: The 4-Dehydroanilinium Ion." L. J. Chyall and H. I. Kenttämä, 208th National Meeting of the American Chemical Society, Washington, DC, August 21-25, 1994: Abstract ORGN 404.
8. "Astrophysical Thermochemistry: The Heats of Formation of C₃H₂ Isomers." L. J. Chyall and R. R. Squires, 43rd ASMS Conference on Mass Spectrometry, Atlanta, GA, May 21-26, 1995: Abstract WOE 11:50.

Invited Lectures

1. "Environmentally Friendly Fire Suppression Technology." Department of Chemistry, Purdue University, West Lafayette, IN. April 8, 1997.
2. "The Proton Affinity and Absolute Heat of Formation of Trifluoromethanol." Joint Institute Laboratory for Astrophysics, University of Colorado, Boulder, CO. March 1, 1996.
3. "Understanding the Atmospheric Fate of Hydrofluorocarbons: Thermochemistry of Trifluoromethanol." Aeronomy Laboratory, National Oceanic and Atmospheric Administration, Boulder, CO. February 29, 1996.

Dissertation

Chyall, L. J. The synthesis and thermal rearrangements of 7,7-dibromo-*trans*-bicyclo[4.1.0]hept-3-ene and 7,7-dichloro-*trans*-bicyclo[4.1.0]hept-3-ene. (1991) 192 pp. Avail.: Univ. Microfilms Int., Order No. DA9209417 From: Diss. Abstr. Int. B 1992, 52(10), 5264.

Attachment C

CARMEN A. CROSS, MD, FACEP

DATE OF BIRTH

[REDACTED]

PLACE OF BIRTH

[REDACTED]

SUMMARY OF QUALIFICATIONS

Thirty-nine years of clinical and administrative experience in a high acuity/volume Level II Emergency Department/Trauma Unit.

Extensive clinical/administrative experience in Emergency Medicine, Occupational Medicine, Staff Health and Allied Health.

Founder and Administrator of Emergency Medicine Physician Assistant Program.

Established medical-legal expert in the field of Emergency Medicine and Allied Health.

Executive Consultant in Emergency Department Management and TQI, Gerson Lehrman Group , NY, NY.

Specialty Consultant in Emergency/Trauma Medicine/EMTALA

Extensive teaching experience in Emergency Medicine, Allied Health, Emergency Nursing and EMS.

EDUCATION

1967-1971 Notre Dame High School, Utica, NY (CL)

1971-1975 Syracuse University, BS, Major: Biology, Minors: Theater, Music, Psychology, Cultural Anthropology (SCL)

1975-1979 New York Medical College, Medical Degree.

1979-1981 Brown University Affiliated Hospitals, Rhode Island. Internal Medicine

LICENSES/CERTIFICATIONS

[REDACTED]

[REDACTED]

[REDACTED]

• E-MAIL: CARMENCROSS@MAC.COM

National Board of Medical Examiners- Diplomat 1979

New York Medical License- 142483

Board Certified- ABEM 1989, Recertified November 1999; Recert. Dec. 2009

Fellow- American College of Emergency Physicians 1988- Present

DEA (NYS)- AC9321934

ACLS/ATLS/PALS- Instructor/Provider since 1984

Certification - Emergency Toxicology, 1985, Bellevue Hospital, Goldfrank Toxicology Series

Certification - Clinical Electrocardiography, ACEP, 1984

Certification - Wound/Ballistics, American Health Consultants, 1988

Certification- Emergency Medicine Ultrasound, 1996. Lincoln Hospital, Department of Emergency Medicine.

Advanced Airway Management, 1990, New York-Presbyterian Hospital.

PROFESSIONAL ACTIVITY

2001-Present Senior Attending, Emergency/Regional Trauma Center, St. Elizabeth's Medical Center, Utica, NY. Director: Dr. Afsar Khan (phone: 315-249-6697)

2007-present Volunteer Physician, Pines Care Center, Fire Island Pines, NY

2002- 2003 Interim Chairman, Emergency Medicine, Kingston Hospital, Kingston, New York

2002-2005 , Clinical Provider, Special Consultant, Dept. of Emergency Medicine, Kingston Hospital, Kingston, NY

2000- 2001 Emergency Medicine Management Consulting, Guidance Corporation, NY, NY.

2000- 2002 Clinical Provider/EMS Committee Chairman/ED Task Force Chairman , Catholic Hospital Systems, Archdiocese of New York

2001-2004 Clinical Provider/ Management Consultant, Kingston Hospital, Kingston, New York, Department of Emergency Medicine. Director: Dr. Ferdinand Anderson (phone: 845-431-0569).

1988-Present Medical Malpractice Expert Consultant, Emergency Medicine, Emergency Medicine Allied Health, EMTALA, Emergency

Medicine Management

1990-Present	Merit Review/ Medical Expert, Emergency Medicine.
1999-2001	Special Consultant in Emergency Medicine, OIG.
1987-2000	Chairman , Department of Emergency Medicine Columbia Memorial Hospital (CMH), NY. Census- 40,000. Level II Trauma Facility, Chest Pain Unit, Urgicare Center.
1981-1988	Associate Chief, Department of Emergency Medicine, CMH , NY.
1981-2000	Attending Emergency Physician CMH, NY.
1990-2000	Medical Director, Staff Health Services, CMH, NY.
1998-2000	Medical Director, Chest Pain Unit, CMH, NY
1990-2000	Medical Director, Emergency Medicine PA Program,CMH, NY
1990-2000	Medical Director, Occupational Medicine, CMH, NY.
1998-2000	Medical Director, Sexual Assault Nurse Examiner Program, CMH, New York
1983-2000	Chairman, Quality Assurance Committee, Department of Emergency Medicine, CMH, New York
1998-2000	Chairman , Emergency Medicine Community Reach Program
1982-2000	Chairman, Base Station Medical Control, Department of Emergency Medicine, CMH, Hudson, NY.
1982-2000	Executive Member, REMO of Central New York.
1982-1986	Chairman, Invasive Procedures Committee, CMH, NY.
1982-1986	Chairman, Infection Control Committee, CMH, NY.
1989-2000	Chairman, Emergency Medical Services Committee, CMH, NY
1989-2000	Department Chief, Medical Executive Committee, CMH, NY
1994-2000	Associate Chairman/Chairman, Medical Bylaws Committee, CMH, NY
1981-2000	Medical Instructor/Advisor, EMS Paramedic Program,

	Columbia County
1989-2000	Chairman, Peer Review Committee, Emergency Medicine, CMH, NY
1994-2000	Co-Chairman, Psychiatry/Emergency Medicine Focus Task Committee
1996-1998	Physician Chairperson, New Emergency Wing Architectural Planning Committee, CMH, NY
1996-1998	Co-Chairman, Fund Campaign, Kellner Emergency Medicine/Surgery Building Project, CMH, NY
1990-2000	Chairman, Trauma Committee, CMH, NY
1982-2000	Physician Liaison, Columbia/Greene County Department of Mental Health
1982-2000	Executive Physician, County Disaster Planning Committee, Columbia County
1981-2000	Coroner's Physician, Columbia County

EDUCATIONAL POSITIONS

2001-Present	Senior Lecturer Trauma and Emergency Medicine, St. Elizabeth Medical Center, Trauma Unit, Utica, NY
1981-2000	Director and Senior Lecturer, Emergency Medicine Grand Rounds, CMH, NY
1981-2000	Instructor, EMS Paramedic Program, CG Com College
1981-Present	ACLS/ATLS/PALS Instructor-Provider
1989-2000	Senior Advisor/Preceptor, Albany Physician Assistant Program, Albany Medical College
1996-1999	Student Preceptor Program, Nurse Practitioners in Emergency Medicine, Russell Sage University, Pace University
1992-2000	Editor-in-Chief, Emergency Medicine Quarterly Community Bulletin
1997-1999	Senior Editor, Columbia Emergency Medicine Website

PRESENTATIONS AND LECTURES/PUBLICATIONS

Individual Topics/Titles/Dates available on request under separate cover.

1973-1975	Direct Current Potentiometry and Autism. International Journal for Biologic Psychiatry. Research in Autism presented at the International Conference for Biologic Psychiatry, Boston Hilton, Boston, Mass.
1973-1975	Research Partner- Trans-cephalic DC Potentiometry in Autism/ Autism Research Center, Marcy State Hospital Research Division, Marcy, NY.
1981-2000	Columbia-Greene Community College Paramedic Program. Lectures in pre-hospital care and Emergency Medicine.
1990-2000	Emergency Medicine Grand Rounds. Topics in Emergency Medicine for Physicians, Nurses and Allied Health. CMH. Case presentations
1994-2000	Lecture Series in Emergency Psychiatry, Department of Psychiatry and Emergency Medicine, CMH, NY. Case presentations.
1994-2000	Emergency Medicine Community Bulletin. Multiple topics for the lay readers of Columbia and Greene Counties.

PROFESSIONAL MEMBERSHIPS

1980-Present	American College of Emergency Physicians
1989-Present	Fellow, American Board of Emergency Medicine
1980-1986	American Medical Association.
1981-Present	Physician Member, NY Chapter, ACEP
1981-2000	Columbia County Medical Society
2000-Present	Oneida County Medical Society

INTERESTS AND ACTIVITIES

Sailing, Swimming, Yoga, Music-Instrumental and Composition

Physician Volunteer- AIDS Crisis Unit, City of New York

Physician Volunteer- Medicine Without Borders, SIDA Resource Division, Paris, France

REFERENCES

Stewart Kaufman, MD President, Medical Staff, CMH. Chairman-Medical Executive Committee, 71 Prospect Ave, Hudson, NY 12534. Phone:518-828-0489 (22 years)

Steven Kaufman, MD Former Chief, Department of Emergency Medicine, CMH, 71 Prospect Ave, Hudson, NY 12534. Phone:413-274-6248 (22 years)

Louis DiGiovanni, MD Chief of Surgery, CMH, 71 Prospect Ave, Hudson, NY 12534 Phone: 518-828-7644 (30 years)

Paul Snapper, MD President Capitol District PHO, CMH, 71 Prospect Avenue, Hudson, NY 12534 Phone: 518-943-5760 (18 years)

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Kev Enu, MD Chairman, Division of Urology, CMH, Hudson, NY Phone: 518-828-7601

John Matthews, MD Chief of Anesthesiology, CMH, Hudson, NY Phone: 518-828-7601 (10 years)

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Sister Rose Vincent, CEO Emeritus, St. Elizabeth Medical Center, Utica, NY (315)798-8111

Sister Johanna, CEO, St. Elizabeth Med. Center, Utica, NY (315)798-8111

Further references will be furnished upon request.

Attachment D

CURRICULUM VITA

KINAM PARK

Purdue University
Weldon School of Biomedical Engineering

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kinam.com; kinampark.com

October 2019

TITLE: Showalter Distinguished Professor of Biomedical Engineering
Professor of Pharmaceutics

Education: B.S. in Pharmacy 1971-1975 Seoul National University, Seoul, Korea
Ph.D. in Pharmaceutics 1979-1983 University of Wisconsin, Madison, WI
Postdoc in Chem. Eng. 1983-1985 University of Wisconsin, Madison, WI

Academic Appointment

7/06 - present	Showalter Distinguished Professor of Biomedical Engineering Purdue University
6/01 - present	President, Akina, Inc.
7/98 - present	Professor, Department of Biomedical Engineering, Purdue University
7/94 - present	Professor, Department of Pharmaceutics, Purdue University
7/90 - 6/94	Associate Professor, Department of Pharmaceutics, Purdue University
2/86 - 6/90	Assistant Professor, Department of Pharmaceutics, Purdue University
5/85 - 1/86	Research Assistant Professor Department of Pharmaceutics, University of Utah
4/83 - 4/85	Postdoctoral Research Associate Department of Chemical Engineering, University of Wisconsin
1/79 - 3/83	Research Assistant Department of Pharmaceutics, University of Wisconsin
3/75 - 7/77	Served in the Korean Army as a lieutenant

Awards and Honors

NIH New Investigator Research Award (1986)
Achievement Award in 1989 IBM Supercomputing Competition (1990)
Young Investigator Award: Controlled Release Society (1992)
Controlled Release Society-Merck Award for the Outstanding Paper in the Ag/Vet field (1997)
University Faculty Scholar, Purdue University (1999)
Clemson Award (the basic research category) of Society for Biomaterials (2001)
Research Achievement Award (Pharmaceutics and Drug Delivery Section) (2001)
Controlled Release Society-NanoSystems Outstanding Pharmaceutical Paper Award (2004)
Controlled Release Society Founders Award (2004)
Louis W. Busse Lectureship of School of Pharmacy, University of Wisconsin (2008)
Sigma Xi Research Award (the Purdue University Chapter) (2009)
Advisory Professor for Medical Science Research at Kyungpook National University (2009-2012)
The Nagai Foundation Tokyo Distinguished Lectureship (2010)
Purdue Cancer Research Award by Lafayette Lions Club (with Professor Ji-Xi Cheng) (2011)
Kyung Hee University International Scholar (2012)
Visiting Professor of Heilongjiang University of Chinese Medicine, China (2012)
Visiting Professor of Ajou University, Korea (2013)
Thomson Reuters' list of "The World's Most Influential Scientific Minds. 2014 (2014)
Korean-American Society in Biotech and Pharmaceuticals (KASBP)-Daewoong Award (2014)
Featured in Indiana at 200. A Celebration of the Hoosier State (2015)
Ashland Inc. Distinguished Lecturer at the University of Kentucky (2015)
Controlled Release Society Distinguished Service Award (2015)
Willis A. Tacker Prize for Outstanding Teaching in Weldon School of Biomedical Engineering (2015)
The 2015 Purdue Innovator Hall of Fame Inductee (2015)
Distinguished Scholar, the Chinese University of Hong Kong (2016)
Special Government Employee at FDA CDER (2016)
Clarivate Analytics' list of "Most Influential Scientific Minds. Highly Cited Researchers (2016)
Clarivate Analytics' list of "Highly Cited Researchers (2017)
The University of Auckland Distinguished Visitor Award (2017)
Clarivate Analytics' list of "Highly Cited Researchers (2018)
The 2018 CRS Foundation Award (honoring Kinam Park with Student Travel Grant Program) (2018)

Controlled Release Society-3M Drug Delivery Systems Graduate Student Outstanding Research Award
in Drug Delivery (Yoon Yeo: Controlled Release Society, 2003)
AAPS Outstanding Graduate Student Research Award in Pharmaceutical Technologies
(Mentoring Yong Qiu: American Association of Pharmaceutical Scientists, 2003)
AAPS Outstanding Graduate Student Research Award in Pharmaceutical Technologies
(Mentoring Yoon Yeo: American Association of Pharmaceutical Scientists, 2004)
Drug Delivery Special Interest Group Outstanding Contribution to the Society for Biomaterials
(Eunah Kang: Society for Biomaterials 2007)

Board of Governors of the Controlled Release Society (1993-1996)
Fellow, American Association for Pharmaceutical Scientists (AAPS) (1993)
President of the Korean-American Pharmaceutical Scientists Association (1995-97)
Fellow, American Institute for Medical and Biological Engineering (1996)
Fellow, Biomaterials Science and Engineering of the Society for Biomaterials (2000)
President of the Controlled Release Society (2001-2002)
Fellow, Controlled Release Society (2010)

Professional Activities

Advisory Board

Advisory Board of the Molecular Modeling Conference (1994)
Advisory Panel on Polymeric Excipients, USP (1995-1999)
ACS Books Advisory Board (1997-2000)
Advisory Panel on Current Drugs (1997-1999)
Scientific Advisory Board, International Symposium on the Frontiers in Biomedical Polymers Applications (2000-2001)
Scientific Advisory Board, International Symposium on Recent Advances in Drug Delivery Systems (2000-2001)
Advisory Panel on Excipients: Substance and Characterization Expert Committee, USP (2000-2005)
Scientific Program Committee of the 2nd Pharmaceutical Sciences World Congress (PSWC) (2004)
Scientific Advisory Board, Delsite, Inc. (2004-2008)
Scientific Advisory Board, International Nanomedicine and Drug Delivery Symposium (2005-)
Scientific Advisory Board, Soleira Laboratories (2006-2008)
Scientific Advisory Board, Boston Scientific (2006-2008)
Scientific Advisory Board, Lohmann Therapie-Systeme AG (2006-2012)
Scientific Advisory Board, European Symposium on Controlled Drug Delivery (2006-2009)
Scientific Advisory Board, China International Pharmaceutical Technologies Conference 2007 (2006-2008)
Scientific Organizing Committee for Micro 2007, the 16th International Symposium on Microencapsulation (2007)
International Advisory Board, CIMTEC 2008 the 3rd International Conference on Smart Materials, Structures and Systems (2007-2008)
Dean's Faculty Advisory Committee, Purdue University, College of Engineering (2007-2013)
Engineering Named Professorships Committee, Purdue University, College of Engineering (2007-2014)
Provost Search Committee, Purdue University (2007-2008)
Board of Directors & Chairman of Fellowship Committee, CRS Foundation (2008-2013)
International Advisory Board, CIMTEC 2010 the 5th Forum on New Materials & 9th International Conference on Medical Applications of Novel Biomaterials and Nano-biotechnology (2009-2012)
Drug Delivery Scientific Advisory Board, Genentech (2010-2015)
The International Symposium on Biomaterials and the China-Japan-Korea (Asia 3) Foresight Joint Symposium on Gene Delivery, Guilin, Guangxi, China (2010-2011)
Chairman, Dean's Faculty Advisory Committee, Purdue University, College of Engineering (2010-2012)
International Scientific Advisory Board, School of Pharmacy at Queen's University Belfast (2011)
Scientific Committee, the 19th International Symposium on Microencapsulation, Pamplona, Spain (2012-2013).
International Advisory Board, 20th International Symposium on Microencapsulation. IMS2015 Boston (2014)
External Advisor for the Center of Biological Research Excellence at the University of South Carolina (2014-2015)
Chair, the Annual Meeting Programme Committee for the Controlled Release Society conference in 2016.
Faculty Awards and Recognition (FAR) committee, College of Engineering representative (2015-2018)
Scientific Advisory Board, the International Conference on Biomaterials Science in Tokyo (2016)
International Advisory Board, CIMTEC 2018 the 8th Forum on New Materials & 12th International Conference on Medical Applications of Advanced Biomaterials and Nano-biotechnology (2017-2020)

External Advisor for Internal Projects at Korea Institute of Science and Technology (KIST) (2017)
International Organizing/Advisory Committee, 5th Symposium on Innovative Polymers for Controlled Delivery, Suzhou, China (2018)

Editorial Board

Journal of Biomaterials Science- Polymer Edition (1993-)
Journal of Bioactive and Compatible Polymers (1993-)
Journal of Controlled Release (1997-2005)
Colloids and Surfaces B: Biointerfaces (1997-)
Archives of Pharmacal Research (1998-)
PharmSci (official electronic journal of AAPS) (1999-2009)
PharmSciTech (official electronic journal of AAPS) (2001-2009)
Drug Delivery Technology (2002-)
Advanced Drug Delivery Reviews (2003-)
Biomaterials Research (2003-)
Encyclopedia of Pharmaceutical Technology (2003-)
Macromolecular Research (2004-)
Journal of Pharmacy and Pharmacology (2004-)
Journal of Biopharmaceutics and Biotechnology (2005-)
CRS Books (2006-)
Drugs in Pharmaceutical Sciences Series, Taylor & Francis & Informa (2007-)
Journal of Drug Delivery Science and Technology (2008-)
Nanomedicine: Nanotechnology, Biology and Medicine (2010-2011)
Nano Reviews (2010-)
Drug Delivery and Translational Research (2010-)
Frontiers in Drug Delivery Biotechnology (2010-)
Experimental Biology and Medicine (2012-2015)
Journal of Hydrogels (2013-)
Biomaterials Research (2014-)
Regenerative Engineering and Translational Medicine (2015-)
International Journal of Pharmaceutics (2018-)

Journal Editor

Associate Editor, Pharmaceutical Research (1995-2004)
Book Review Editor, Pharmaceutical Research (1996-2004)
Guest Editor, Colloids and Surfaces B: Biointerfaces (1998-1999)
Guest Editor, Advanced Drug Delivery Reviews (2001-2002)
Editor, Americas, Journal of Controlled Release (2005)
Editor-in-Chief, Journal of Controlled Release (2005-)

NIH Study Section

NIH Pharmacology Study Section member (1996-2001, 2003)
NIH Bioengineering, Technology, and Surgical Sciences Study Section member (2005-2009)
Member, College of CSR Reviewers, NIH (2010-2013, 2016)

Special Reviewer of NIH Study Sections

Surgery and Bioengineering Study Section (1991, 1995-1997, 1999, 2004)
Surgery, Anesthesiology, & Trauma Study Section (1992-1994)
Special Study Section SSS-8 (1995)
Pharmacology Special Study Section, Chairman (2001, 2002, 2003)
National Cancer Institute Special Emphasis Panel (2005)
Member of NIH SBIR Special Study Sections

Diabetes and Digestive and Kidney Diseases (1990, 1991, 1993), Pharmacology (1990, 1992, 1993), Physiological Sciences (1990), Reproductive Endocrinology (1990-1992, 1994-1996, 1999), Multidisciplinary Special Emphasis (1994, 1995), NIDDK (2009).

Membership in Academic, Professional, and Scholarly Societies

American Association of Pharmaceutical Scientists
American Chemical Society
Controlled Release Society
Society for Biomaterials
Biomedical Engineering Society

Books

- 1) Park, K., Shalaby, S.W.S., and Park, H.: *Biodegradable Hydrogels for Drug Delivery*, Technomic Publishing Co., Inc., Lancaster, PA, 1993, 252 pages.
- 2) Ottenbrite, R., Hwang, S., and Park, K., Eds.: *Hydrogels and Biodegradable Polymers for Bioapplications* (ACS Symposium Series 627), American Chemical Society, Washington, DC, 1996, 268 pages.
- 3) Park, K., Ed.: *Controlled Drug Delivery: Challenges and Strategies*, American Chemical Society, Washington, DC, 1997, 629 pages.
- 4) Park, K. and Mrsny, R., Eds.: *Controlled Drug Delivery: Designing Technologies for the Future* (ACS Symposium Series 752), American Chemical Society, Washington, DC, 2000, 459 pages.
- 5) Park, K.D., Kwon, I.C., Yui, N., Jeong, S.Y. and Park, K., Eds.: *Biomaterials and Drug Delivery toward New Millennium*, Han Rim Won Publishing Co., Seoul, Korea, 2000, 691 pages.
- 6) Yui, N., Mrsny, R., and Park, K., Eds.: *Reflexive polymers and hydrogels: Understanding and designing the fast-responsive polymeric systems*, CRC Press, Boca Raton, FL, 2004. 452 pages.
- 7) Morishita, M. and Park, K., Eds.: *Biodrug Delivery Systems: Fundamentals, Applications and Clinical Development*, (Volume 194 of the Drugs and the Pharmaceutical Sciences Series), Informa Healthcare, New York, NY, 2010. 471 pages.
- 8) Ottenbrite, R.M., Park, K., Okano, T., and Peppas, N.A., Eds.: *Hydrogels Handbook*, Springer, 2010, 432 pages.
- 9) Wen, H. and Park, K., Eds.: *Oral Controlled Release Formulation Design and Drug Delivery: Theory to Practice*, John Wiley & Sons, New York, NY, 2010. 363 pages.
- 10) Bae, Y.H., Mrsny, R., and Park, K., Eds.: *Cancer Targeted Drug Delivery: An Elusive Dream*, Springer, New York, 2013, 720 pages.
- 11) Park, K., Ed.: *Biomaterials for Cancer Therapeutics: Diagnosis, Prevention, and Therapy*, Woodhead Publishing Ltd., Oxford, UK, 2013, 528 pages.
- 12) Hillery, A. and Park, K., Eds.: *Drug Delivery: Fundamentals and Applications*, Second Edition, CRC Press/Taylor & Francis Group, Boca Raton, FL, 2016. ISBN: 978-1-4822-1771-1. 614 pages.
- 13) Park, K., Ed.: *Biomaterials for Cancer Therapeutics: Evolution and Innovation*, Elsevier., 2019, in press.

Journal Special Issues

- 1) Park, K. Ed., *Protein- and Cell-Repellent Surfaces*, Colloids and Surfaces B: Biointerfaces, Elsevier Science, Vol. 18 (No. 3-4), 2000. (with Editorial on p.167).

- 2) Park, K., Ed., *Recent Developments in Hydrogels*, Advanced Drug Delivery Reviews, Elsevier Science, Vol. 54 (1), 2002. (With Preface on p.1).

Refereed Articles

- 1) Park, K. and Robinson, J.R.: Bioadhesive polymers as platforms for oral-controlled drug delivery: method to study bioadhesion, *Int. J. Pharm.* 19: 107-127, 1984.
- 2) Park, K. and Cooper, S.L.: Importance of composition of the initial protein layer and platelet spreading in acute surface-induced thrombosis, *Trans. Amer. Soc. Artif. Inter. Organs* 31: 483-488, 1985.
- 3) Park, K., Mosher, D.F., and Cooper, S.L.: Acute surface-induced thrombosis in the canine ex vivo model: Importance of protein composition of the initial monolayer and platelet activation, *J. Biomed. Mater. Res.* 20: 589-612, 1986.
- 4) Park, K., Albrecht, R.M., Simmons, S.R., and Cooper, S.L.: A new approach to study the adsorbed protein layer on biomaterials: Immunogold staining techniques, *J. Colloid Interf. Sci.* 111: 197-212, 1986.
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- 7) Park, K., Gerndt, S.J., and Cooper, S.L.: The effect of fibrinogen sialic acid residues on *ex vivo* platelet deposition on biomaterials, *Thromb. Res.* 43: 293-302, 1986.
- 8) Park, K., Simmons, S.R., and Albrecht, R.M.: Surface characterization of biomaterials by immunogold staining - quantitative analysis, *Scanning Microscopy*, 1: 339-350, 1987.
- 9) Pitt, W.G., Young, B.R., Park, K., and Cooper, S.L.: Plasma protein adsorption: in vitro and ex vivo observations. *Makromol. Chem., Macromol. Symp.*, 17: 453-465, 1988.
- 10) Park, K.: Enzyme-digestible swelling hydrogels as platforms for long-term oral drug delivery: synthesis and characterization. *Biomaterials*, 9: 435-441, 1988.
- 11) Park, K., Gerndt, S.J., and Park, H.: Patchwise adsorption of fibrinogen on glass surfaces and its implication in platelet adhesion. *J. Colloid Interf. Sci.*, 125: 702-711, 1988.
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- 13) Park, K. and Park, H.: Application of video-enhanced interference reflection microscopy to the study of platelet-surface interactions, *Scanning Microscopy*, Suppl. 3: 137-146, 1989.
- 14) Park, K.: A new approach to study mucoadhesion: Colloidal gold staining, *Int. J. Pharm.*, 53: 209-217, 1989.
- 15) Park, K., Mao, F. W., and Park, H.: Morphological characterization of surface-induced platelet activation, *Biomaterials*, 11:24-31, 1990.
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- 17) Lu, D.R. and Park, K.: Protein adsorption on polymer surfaces: calculation of adsorption energies, *J. Biomater. Sci. Polymer Edn.*, 1:243-260, 1990.
- 18) Lu, D.R. and Park, K.: A three-dimensional protein graphic program, *Computer Physics Communications*, 60: 257-263, 1990.

- 19) Park, K., Mao, F. W., and Park, H.: The minimum surface fibrinogen concentration necessary for platelet activation on dimethyldichlorosilane-coated glass, *J. Biomed. Mater. Res.*, 25: 407-420, 1991.
- 20) Lu, D.R., Lee, S.J., and Park, K.: Calculation of solvation interaction energies for protein adsorption on polymer surfaces, *J. Biomater. Sci. Polymer Edn.*, 3: 127-147, 1991.
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- 22) Shalaby, W.S.W., Peck, G., and Park, K.: Release of dextromethorphan hydrobromide from freeze-dried enzyme-degradable hydrogels, *J. Control. Release*, 16: 355-364, 1991.
- 23) Park, K. and Lu, D.R.: Communication to the editor: Authors' reply, *J. Biomater. Sci. Polymer Edn.*, 2: 321-322, 1991.
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- 29) Shalaby, W.S.W., Chen, M., and Park, K.: A mechanistic assessment of enzyme-induced degradation of albumin-crosslinked hydrogels, *J. Bioact. Compat. Polymers*, 7: 257-274, 1992.
- 30) Amiji, M. and Park, K.: Prevention of protein adsorption and platelet adhesion on surfaces by PEO/PPO/PEO triblock copolymers, *Biomaterials*, 13: 682-692, 1992.
- 31) Amiji, M. and Park, K.: Surface modification by radiation-induced grafting of PEO/PPO/PEO triblock copolymers, *J. Colloid Interf. Sci.*, 155: 251-255, 1993.
- 32) Tseng, Y.C., Kim, J., and Park, K.: Photografting of albumin onto dimethyl-dichlorosilane-coated glass, *J. Biomaterials Applications*, 7: 233-249, 1993.
- 33) Shalaby, W.S.W., Jackson, R., Blevin, W.E., and Park, K.: Synthesis of enzyme-digestible, interpenetrating hydrogel networks by gamma-irradiation, *J. Bioact. Compat. Polymers*, 8: 3-23, 1993.
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- 35) Tseng, Y.C., Mullins, W.M., and Park, K.: Albumin grafting onto polypropylene by thermal activation, *Biomaterials*, 14: 392-400, 1993.
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- 37) Park, H. and Park, K.: Role of polymers in pharmaceutical products, *ACS Symp. Ser.*, 540: 2-15, 1994.
- 38) Amiji, M. and Park, K.: Surface modification of polymeric biomaterials with PEO: A steric repulsion approach, *ACS Symp. Ser.*, 540: 135-146, 1994.
- 39) Bowersock, T.L., Shalaby, W.S.W., Samuels, M.L., White, M.R., Lallone, R., Levy, M., Ryker, D., and Park, K.: Poly(methacrylic acid) hydrogels as carriers of bacterial exotoxins in an oral vaccine for cattle, *ACS Symp. Ser.*, 540: 288-296, 1994.

- 40) Kamath, K. and Park, K.: Preparation and characterization of enzyme-digestible hydrogels from natural polymers by gamma-irradiation, *ACS Symp. Ser.*, 545: 55-65, 1994.
- 41) Lee, S.J. and Park, K.: Study of polymer-solvent interactions using computational chemistry, *ACS Symp. Ser.*, 545: 221-233, 1994.
- 42) Bowersock, T.L., Shalaby, W.S.W., Blevins, W.E., Levy, M., and Park, K.: Poly(methacrylic acid) hydrogels for rumen bypass and the delivery of oral vaccines to ruminants, *ACS Symp. Ser.*, 545: 214-220, 1994.
- 43) Amiji, M.A. and Park, K.: Analysis on the surface adsorption of PEO/PPO/PEO triblock copolymers by radiolabeling and fluorescence techniques, *J. Applied Polymer Sci.*, 52: 539-544, 1994.
- 44) Kamath, K. and Park, K.: Surface modification of polymeric biomaterials by albumin grafting using gamma-irradiation, *Journal of Applied Biomaterials*, 5: 163-173, 1994.
- 45) Kamath, K., Park, H., Shim, H.S., and Park, K.: Albumin grafting on dimethyldichlorosilane-coated glass by gamma-irradiation, *Colloids and Surfaces. B. Biointerfaces*, 2: 471-479, 1994.
- 46) Bowersock, T.L., Shalaby, W.S.W., Levy, M.L., Samuels, M.L., Lallone, R., White, M.R., Borie, D.L., Lehmyer, J., and Park, K.: Evaluation of an orally administered vaccine using hydrogels containing bacterial exotoxins of *Pasteurella Haemolytica* in cattle, *Am. J. Veterinary Res*, 55(4): 502-509, 1994.
- 47) Lee, S.J. and Park, K.: Protein interaction with surfaces: Separation distance-dependent interaction energies, *J. Vacuum Science and Technology A*, 12(5): 2949-2956, 1994.
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- 16) Application of quantitative colloidal gold staining to the study of mucin-polymer interactions, Scanning '91, Atlantic City, NJ, April 10-12, 1991.
- 17) Development of long-term oral drug delivery systems using enzyme-digestible swelling hydrogels, Syntex Research, Palo Alto, CA, June 10, 1991.
- 18) Application of quantitative colloidal gold staining to the study of mucin-polymer interactions, 3M Life Sciences Sector, St. Paul, MN, June 13, 1991.
- 19) Prevention of platelet adhesion and activation by surface modification, 3M Life Sciences Sector, St. Paul, MN, June 14, 1991.
- 20) Hydrogel systems, 204th ACS National Meeting, Washington, D.C., August 23, 1992.
- 21) Hydrogel systems in pharmaceuticals, 1992 Annual Meeting of AAPS, PDD Symposium on Polymer Science: Unique Applications in the Pharmaceutical Industry, San Antonio, TX, November 17, 1992.
- 22) Oral vaccination using hydrogels, Miles Inc., Animal Health Products, Shawnee Mission, KS, February 24, 1993.
- 23) Biodegradable hydrogels for delivery of protein drugs, The 205th American Chemical Society National Meeting, Division of Polymer Chemistry, Denver, CO, April 1, 1993.
- 24) Evaluation of bioadhesion by colloidal gold staining, Gliatech, Inc., Cleveland, OH, June 11, 1993.
- 25) Surface modification of biomaterials, Korea Institute of Science & Technology, Seoul, Korea, June 25, 1993.
- 26) Prevention of protein adsorption and cell adhesion, Gordon Conference on Biocompatibility and Biomaterials, Tilton, NH, July 11, 1993.
- 27) Smart hydrogels for pharmaceutical applications, PharmTech Conference, Atlantic City, NJ, September 22, 1993.
- 28) Protein interactions with surfaces, American Vacuum Society, Orlando, FL, November 15, 1993.
- 28) New methods for modification of polymeric biomaterials, BSI Corporation, Eden Prairie, MN, November 5, 1993.
- 29) Protein interactions with surfaces, American Vacuum Society, Orlando, FL, November 15, 1993.
- 30) Surface modification of biomaterials, Cedars-Sinai Medical Center, Los Angeles, CA, November 22, 1993.
- 31) Smart hydrogels, WCCR Literature Meeting, Purdue University, West Lafayette, IN, April 22, 1994.
- 32) Polysaccharide hydrogels for controlled drug delivery, Frontiers in Carbohydrate Research Conference, West Lafayette, IN, May 10, 1994.

- 33) Surface modification for prevention of protein adsorption, AAPS Midwest Regional Meeting, Chicago, IL, May 23, 1994.
- 34) Oral vaccination of cattle via hydrogel delivery systems, The 21st International Symposium on Controlled Release of Bioactive Materials, Nice, France, June 27, 1994.
- 35) Surface modification of biomaterials for the prevention of protein adsorption and cell adhesion, Dept. of Biomedical Engineering, Duke University, Durham, NC, October 17, 1994.
- 36) Development of modulated insulin delivery systems: prospects and limitations, Korea Basic Science Center, Seoul, Korea, October 24, 1994.
- 37) Oral vaccination hydrogel systems, Second International Symposium on Biomaterials and Drug Delivery Systems, Korea Institute of Science and Technology, Seoul, Korea, October 25, 1994.
- 38) Recent advances in drug delivery systems using hydrogels, *Pacific Corporation*, Seoul, Korea, October, 28, 1994.
- 39) Surface modification of biomaterials, Center of Membrane Sciences, University of Kentucky, Lexington, KY, December 6, 1994.
- 40) Synthesis of novel sucrose-derived hydrogels and hydrogel foams for pharmaceutical applications, The Sugar Association, Washington, D.C., March 7, 1995.
- 41) Oral vaccination hydrogel systems, The Seventh International Symposium on Recent Advances in Drug Delivery Systems, Salt Lake City, UT, February 28, 1995.
- 42) Surface modification for the prevention of protein adsorption and cell adhesion, College of Pharmacy, University of Michigan, Ann Arbor, MI, March 8, 1995.
- 43) Stent regulation of the vascular microenvironment, The 41st Annual Conference of ASAIO (American Society for Artificial Internal Organs), Chicago, IL, May 6, 1995.
- 44) Synthesis of glucose-sensitive phase-reversible hydrogels, 11th International Symposium on Affinity Chromatography and Biological Recognition, San Antonio, TX, May 27, 1995.
- 45) Smart hydrogels for pharmaceutical applications, Strategies for new drug and vaccine development, 5th Annual Meeting of the Society of Biomedical Research, Washington, D.C., September 15, 1995.
- 46) Surface modification of biomaterials, EE520 Biomedical Engineering Seminar, Purdue University, October 31, 1995.
- 47) Recent trend in pharmaceutical research, Choongwae Pharmaceuticals, Seoul, Korea, December 12, 1995.
- 48) Controlled drug delivery using smart hydrogels, Choongwae Research Labs., Suwon, Korea, December 13, 1995.
- 49) Smart hydrogels, Collagen Corp., Palo Alto, CA, February 6, 1996.
- 50) Issues in the implantable drug delivery systems, 42nd Annual Conference of American Society for Artificial Internal Organs, Washington, D.C., May 3, 1996.
- 51) Controlled drug delivery: Present and future, The Madison Conference on the Pharmaceutical Sciences, 1996, Madison, WI, June 7, 1996.
- 52) Computer simulation in drug delivery and biomaterials research: Oral vaccination hydrogel systems, Third International Symposium on Biomaterials and Drug Delivery Systems, Korea Research Institutes of Chemical Technology, Taejeon, Korea, July 5, 1996.
- 53) Hydrogel foams, Korea Institute of Science & Technology, Seoul, Korea, August 13, 1996.

- 54) A view on future glucose sensors and insulin delivery systems, Cygnus Corp., Redwood City, CA, October 24, 1996.
- 55) Self-regulated insulin delivery and glucose sensing, Fukuoka University, Fukuoka, Japan, May 13, 1997.
- 56) Future of glucose sensing and insulin delivery: A point of view, The First Asian International Symposium on Polymeric Biomaterials Science, Ishikawa, Japan, May 15, 1997.
- 57) New and emerging polymers and hydrogels, Land of Lake Conference on Challenges and Prospects in the Design and Development of Oral Controlled Release Products, Merric, WI, June 4, 1997.
- 58) Biocompatibility of implantable drug delivery systems, CRS-CPA Joint Workshop on Recent Advances in Drug Delivery Science and Technology, Beijing, China, September 20, 1997.
- 59) Biocompatibility of biomaterials, KSP-CRS Joint Symposium on Recent Advances in Drug Delivery and Biomaterials, Seoul, Korea, September 26, 1997.
- 60) Protein adsorption on surfaces with grafted polymers- Experiment, The Purdue Industrial Associates Program on Chemistry of Materials, Purdue University, West Lafayette, IN, October 3, 1997.
- 61) How to respond to reviewers' critiques, The Education Committee sponsored program on How to Write a Research Article at the American Association of Pharmaceutical Scientists 12th National Meeting, Boston, MA, November 4, 1997.
- 62) Fractal analysis of pharmaceutical particles, University of Wisconsin, School of Pharmacy, Madison, WI, January 5, 1998.
- 63) Superporous hydrogel composites: A new class of hydrogels for biomedical and pharmaceutical applications, The Fifth European Symposium on Controlled Drug Delivery, Noordwijk aan Zee, The Netherlands, April 1-3, 1998.
- 64) Drug delivery technology: Use of novel polymers and hydrogels, The AAPS Midwest Regional Meeting, Chicago, IL, May 18, 1998.
- 65) Analysis of glucose-binding molecules, The 25th International Symposium on Controlled Release of Bioactive Materials, Las Vegas, NV, June 23, 1998.
- 66) AFM and fractal analysis of biomaterial microtopography, Microscopy & Microanalysis '98, Atlanta, GA, July 12-16, 1998.
- 67) Oral vaccination using microparticles: potentials and future directions, Pharmaceutical and Analytical & Development, Abbott Laboratories, Chicago, IL, July 24, 1998.
- 68) Surface-grafted PEO chains: Experiments, theoretical analysis, and computer simulation, Non-Fouling Surface Technologies Symposium, Seattle, WA, July 30-31, 1998.
- 69) Superporous hydrogels: Fast responsive hydrogel systems, The American Chemical Society National Meeting. PMSE and Polymer Chemistry Divisions, Boston, MA, August 21-26, 1998.
- 70) Superporous hydrogel composites: synthesis, characterization, and application, The American Chemical Society National Meeting. Polymer Chemistry Divisions, Boston, MA, August 21-26, 1998.
- 71) Fractal analysis of pharmaceutical particles, Korea Institute of Science and Technology, Seoul, Korea, November 10, 1998.
- 72) Superporous hydrogels: medical and pharmaceutical applications, Korea Advanced Institute of Science and Technology, Taejon, Korea, November 11, 1998.
- 73) Fractal analysis of pharmaceutical particles, Korea Research Institute of Chemical Technology, Taejon, Korea, November 11, 1998.

- 74) Development and evaluation of medical devices and materials, The Second International Symposium on Current Status of International Regulation on Food and Drug, Korea Food and Drug Administration, Seoul, Korea, November 13, 1998.
- 75) Superporous hydrogels: medical and pharmaceutical applications, University of Minnesota, Biomedical Engineering Center and Department of Pharmaceutics, Minneapolis, MN, December 3, 1998.
- 76) Hydrogels in drug delivery, Ninth International Symposium on Recent Advances in Drug Delivery Systems, Salt Lake City, UT, February 22, 1999.
- 77) Superporous hydrogels: pharmaceutical and medical applications, Yamanouchi Shaklee Pharma, Palo Alto, CA, March 19, 1999.
- 78) Video-enhanced interference reflection microscopy and video-intensified fluorescence microscopy, The Society for Biomaterials Academic Workshop on Probing and Imaging of Cells and Molecules, Providence, RI, April 28, 1999.
- 79) Degradable, fast-swelling, superporous sucrose hydrogels, Frontiers in Carbohydrate Research-6, West Lafayette, IN, May 12, 1999.
- 80) Characterization of morphological features of crystal surface during dissolution process, University of Utah, Salt Lake City, UT, May 17, 1999.
- 81) Superporous hydrogels: pharmaceutical and medical applications, Alza Corp., Palo Alto, CA, June 15, 1999.
- 82) Surface modified biomaterials: in vitro and in vivo behavior, UWEB Symposium on Devices and Diagnostics in Contact with Blood: Issues in Blood Compatibility at the Close of the 20th Century, Seattle, WA, August 4-6, 1999.
- 83) In vitro and in vivo behavior of surface modified biomaterials, KAIST, Taejon, Korea, August 28, 1999.
- 84) Superporous hydrogels: Synthesis and Application, The 5th International Symposium on Polymers for Advanced Technologies, Waseda University, Tokyo, Japan, August 31-September 5, 1999.
- 85) Pharmaceutical and biomedical applications of superporous hydrogels, Pusan National University, September 13, 1999.
- 86) Surface modified biomaterials: in vitro and in vivo behavior, KIST, Seoul, Korea, September 14, 1999.
- 87) Development of oral paclitaxel delivery systems, Sam Yang Corp., Taejon, Korea, September 17, 1999.
- 88) Pharmaceutical and biomedical applications of superporous hydrogels, Sook Myung Women's University, September 18, 1999.
- 89) Pharmaceutical and biomedical applications of superporous hydrogels, Dong Kook University, September 20, 1999.
- 90) Gastric retention drug delivery systems: Past and present, U.S. Food and Drug Administration, Rockville, MD, September 29, 1999.
- 91) Gastric retention drug delivery systems: Past and present, Kos Pharmaceutical, Edison, NJ, October 14, 1999.
- 92) Superporous hydrogels: pharmaceutical and medical applications, Ohio State University, Columbus, OH, October 28, 1999.

- 93) Superporous hydrogels: pharmaceutical and medical applications, Procter & Gamble Company, Cincinnati, OH, November 1, 1999.
- 94) Polymeric systems for oral controlled delivery, AAPS-Northeast Regional Discussion Group, Hartford, CT, April 24, 2000.
- 95) Modulated insulin delivery using glucose-sensitive sol-gel phase reversible hydrogels, Workshop on Supramolecular Approach to Biological Function, World Biomaterials Congress Workshop, Hawaii, May 15, 2000.
- 96) Superporous hydrogels for oral controlled drug delivery, Chong Kun Dang Corp., Seoul, Korea, May 18, 2000.
- 97) Superporous hydrogels for oral controlled drug delivery, Cheil Jedang Corp., Seoul, Korea, May 19, 2000.
- 98) Polymers in oral drug delivery, Kwang Ju Institute of Science and Technology, Kwang Ju, Korea, May 22, 2000.
- 99) Drug discovery in global economy, Korean Society of Pharmaceutics, Seoul, Korea, May 26, 2000.
- 100) PEO-grafted biomaterials: In vitro and in vivo behavior, Dept. of Chemical and Materials Engineering, University of Kentucky, Lexington, KY, June 30, 2000.
- 101) Modulated insulin delivery using phase-reversible glucose-sensitive hydrogels, The 40th Microsymposium of the Prague Meetings on Macromolecules, the International Union of Pure and Applied Chemistry, July 18, 2000.
- 102) Modulated insulin delivery using phase-reversible glucose-sensitive hydrogels, The 8th Hydrogel, Biodegradable Polymers for Medical Application Workshop, Korea Advanced Institute of Science and Technology, August 24, 2000.
- 103) PEG-modified biomaterials: Lack of in vitro-in vivo correlation, Univ. of Alabama in Huntsville, January 19, 2001.
- 104) Superporous hydrogels: pharmaceutical and biomedical applications, The North Carolina Pharmaceutical Discussion Group, Chapel Hill, NC, March 28, 2001.
- 105) Glucose-sensitive sol-gel reversible hydrogels for modulated insulin delivery, University of North Carolina, Chapel Hill, NC, March 29, 2001.
- 106) Gastric retention devices: Past and present, GlaxoWellcome, Chapel Hill, NC, March 30, 2001.
- 107) Superporous hydrogels for biomedical and pharmaceutical applications, Society for Biomaterials Annual Meeting, Minneapolis, MN, April 26, 2001.
- 108) Polymers in oral drug delivery, University of Maryland, Baltimore, MD, May 3, 2001.
- 109) Gastric retention drug delivery systems: Past and present, Northeastern University, Boston, MA, May 18, 2001.
- 110) Hydrotropic polymers for enhancing water solubility of poorly soluble drugs, The University of Tokyo, Tokyo, Japan, July 8, 2001.
- 111) Hydrotropic polymers for enhancing water solubility of poorly soluble drugs, Japan Advanced Institute of Science and Technology, Ishikawa, Japan, July 9, 2001.
- 112) Hydrotropic polymers for enhancing water solubility of poorly soluble drugs, Korea Institute of Science and Technology, Seoul, Korea, July 13, 2001.
- 113) Hydrotropic polymers for enhancing water solubility of poorly soluble drugs, Korea Research Institute of Chemical Technology, Taejeon, Korea, July 20, 2001.

- 114) Drug delivery, Biomaterials in 2001: State of the art. UWEB Summer Symposium, Seattle, WA, August 21, 2001.
- 115) Superporous hydrogels for pharmaceutical and biomedical applications, University of Georgia, College of Pharmacy, Athens, GA, Nov. 12, 2001.
- 116) Hydrotropic polymers and hydrogels for poorly soluble drugs, Samyang Corp., Taejeon, Korea, November 21, 2001.
- 117) Controlled drug delivery systems: Target areas for product development, Samyang Corp., Yongin-Si, Korea, November 22, 2001.
- 118) Hydrogels in pharmaceutical and biomedical applications, University of Southern California, Los Angeles, CA, December 7, 2001.
- 119) Hydrogels in drug delivery, University of Pennsylvania, Institute of Medicine and Engineering, Philadelphia, PA, January 29, 2002.
- 120) Hydrogels in controlled drug delivery, The 17th Annual Meeting of the Academy of Pharmaceutical Science and Technology, Japan (APSTJ), Shizuoka, Japan, March 30, 2002.
- 121) Polymeric systems in oral controlled drug delivery, Taisho Pharmaceutical Co., Ltd., Saitama-shi, Saitama, Japan, April 2, 2002.
- 122) Polymeric systems in oral controlled drug delivery, Daiichi Pharmaceutical Co., Ltd., Tokyo, Japan, April 2, 2002.
- 123) Hydrogels in drug delivery, AAPS/PDD Conference, Washington, D.C., April 22-24, 2002.
- 124) Novel hydrogels in drug delivery applications, University of Michigan, Ann Arbor, MI, May 15, 2002.
- 125) Hydrogels in drug delivery, University of Toronto, Toronto, Canada, May 30, 2002.
- 126) New platforms for drug delivery, McMaster University, Hamilton, Ontario, Canada, May 31, 2002.
- 127) Polymers and hydrogels in drug delivery: Design and applications, Inhale Therapeutic Systems, Inc., San Carlos, CA, June 12, 2002.
- 128) Novel hydrogels in drug delivery, UK/Ireland chapter of the Controlled Release Society (UKICRS) and 139th British Pharmaceutical Conference, Manchester, United Kingdom, September 24, 2002.
- 129) Nano-structures for delivery of poorly soluble drugs, Nano-biomaterials for drug, gene, and cell therapy, Korea Advanced Institute of Science and Technology, Taejeon, Korea, November 1, 2002.
- 130) New hydrogels for delivery of poorly soluble drugs and proteins, University of Illinois-Chicago, Chicago, IL, November 20, 2002.
- 131) Glucose imprints for modulated insulin delivery, Korean Chemical Society, Polymer Chemistry Division, Taejeon, Korea, December 13, 2002.
- 132) Solvent exchange method: A new process for making reservoir-type microcapsules, 11th International Symposium on Recent Advances in Drug Delivery Systems, Salt Lake City, UT, March 3, 2003.
- 133) Novel methods of making microcapsules based on the solvent exchange method, AAPS Conference on Advances in Pharmaceutical Processing, Parsippany, NJ, June 19, 2003.
- 134) Biomimetic materials, Controlled Release Society Annual Meeting, Glasgow, Scotland, July 22, 2003.
- 135) Solvent exchange method: A new process for making reservoir-type microcapsules, Northeastern University, Boston, MA. September 8, 2003.

- 136) Oral drug delivery: Scientific challenges vs. product development, Oral Drug Delivery Conference, Boston, MA, September 9, 2003.
- 137) Recent progresses in fast melting tablets and delivery of poorly soluble drugs, AAPS Chicago Pharmaceutics Discussion Group Meeting, Chicago, IL, October 9, 2003.
- 138) Hydrotropic polymeric micelle systems for formulation of poorly water-soluble drugs, The 8th European Symposium on Controlled Drug Delivery, Noordwijk aan Zee, The Netherlands, April 7-9, 2004.
- 139) Novel microencapsulation techniques based on the solvent exchange method, Pharmaceutical Sciences World Congress (PSWC2004), 2nd World Congress of the Board of Pharmaceutical Sciences of FIP, Kyoto, Japan, May 31, 2004.
- 140) Nanotechnology: Innovation or rebranding? Debate with Sandy Florence in Pearls of Wisdom, 31st Annual Meeting and Exposition of the Controlled Release Society, Honolulu, HI, June 16, 2004.
- 141) Hydrotropic polymer systems for poorly soluble drugs, 31st Annual Meeting and Exposition of the Controlled Release Society, Honolulu, HI, June 16, 2004.
- 142) Nanopolymeric structures for delivery of paclitaxel, School of Pharmacy, University of Kentucky, September 3, 2004.
- 143) Hydrotropic polymeric nanostructures for delivery of paclitaxel, Nanoparticles. Synthesis, Functionalization and Applications for Targeted Drug Delivery, Cleveland, OH, October 27, 2004.
- 144) Challenges and strategies in drug delivery from coronary stents, Biointerface 2004, Baltimore, MD, October 28, 2004.
- 145) Drug-eluting stents, Boston Scientific, Natick, MA, October 29, 2004.
- 146) Novel methods of making microcapsules based on the solvent exchange method. (Roundtable on Issues in Protein Microencapsulation), 2004 AAPS Annual Meeting, Baltimore, MD, November 10, 2004.
- 147) Recent advances in drug-eluting stents, Korea Research Institute of Chemical Technology, Taejeon, Korea, November 24, 2004.
- 148) Polymers in everyday life, LG Household & Healthcare, Taejeon, Korea, November 24, 2004.
- 149) Recent advances in drug-eluting stents, University of Utah, College of Pharmacy, January 5, 2005.
- 150) Preparation of PLGA microcapsules by the interfacial solvent exchange method, University of Pittsburgh, January 24, 2005.
- 151) Hydrotropic polymers for delivery of poorly soluble drugs, Inha University, Incheon, Korea, July 13, 2005.
- 152) Hydrotropic polymers for delivery of poorly soluble drugs, Boehringer-Ingelheim, Ridgebury, CT, July 20, 2005.
- 153) Oral drug delivery: Scientific challenges and product development, Annual Meeting of the Pharmaceutical Society of Korea, Seoul, Korea, November 29, 2005.
- 154) Polymers used in pharmaceutics, The 2006 AAPS PT Arden Conference, West Point, NY, January 25, 2006.
- 155) Polymer properties for controlled drug delivery, The 2006 AAPS PT Arden Conference, West Point, NY, January 25, 2006.
- 156) Nano/micro drug delivery systems and cellular uptakes, Symposium on Development of New Radiotherapy Technique Using Nano Drug Delivery System, Asan Medical Center, Seoul, Korea, March 10, 2006.

- 157) Controlled drug delivery: From macro to nanotechnologies, Institute of Genetics and Molecular Biology, Seoul National University, Seoul, Korea, June 23, 2006.
- 158) Drug delivery: Evolution into the nanotechnology era, Institute of Bioengineering and Nanotechnology, Republic of Singapore, July 3, 2006.
- 159) Novel methods for microsphere formulation and manufacture, The CMC and Regulatory Issues for Controlled Release Parenterals Workshop at the 33rd Annual Meeting of the Controlled Release Society, Vienna, Austria, July 29, 2006.
- 160) Label-free imaging tools for pharmaceutical and biomedical applications: CARS and SPR, Asan Medical Center, Seoul, Korea, September 5, 2006.
- 161) Nanomedicine: Evolution, revolution, and transformation, Mini Symposium on Molecular Imaging and Nanomedicine, Kyungbook National University, School of Medicine, Daegu, Korea, September 6, 2006.
- 162) Nanomedicine: Evolution, revolution, and transformation, 1st Purdue-KIST Collaborative Symposium on Biomedical Photonics, Korea Institute of Science and Technology, Seoul, Korea, September 7, 2006.
- 163) Translational research in drug delivery, LTS Academy, Andernach, Germany, October 6-8, 2006.
- 164) Imaging study of paclitaxel release from drug-eluting stents, University of Michigan, Ann Arbor, MI, October 19, 2006.
- 165) Nanotechnologies in drug delivery, NanoBio-Tokyo 2006, The University of Tokyo, December 4-7, 2006.
- 166) Fast-melting tablet formulations for controlled release and for large dose drugs, Astellas Pharma, Yaizu, Japan, December 7, 2006.
- 167) Drug-eluting stents: Imaging studies & strategies, Tokyo Women's Medical University Institute of Advanced Biomedical Engineering and Science, Tokyo, Japan, December 8, 2006.
- 168) Nanomedicine: Evolution, revolution, and transformation, The 2007 National Meeting of the Association for Laboratory Automation, Palm Springs, CA, January 27-31, 2007.
- 169) Scientific possibilities for combination products of the future, Symposium on Combination Products in Life Science Industries, Cook Inc. International Headquarters, Bloomington, IN, February 2, 2007.
- 170) Fast-melting tablet formulations for controlled release and for large dose drugs & fast-swelling hydrogels for biomedical applications, Abbott Laboratories, Abbott Park, IL, April 9, 2007.
- 171) Polymeric micelles for delivery of poorly soluble drugs & microcapsules for delivery of protein drugs, Abbott Laboratories, Abbott Park, IL, April 9, 2007.
- 172) What's wrong with the new drug delivery systems? CDER VPLS & ONDQA - cTiPS, USFDA, Rockville, MD, April 23, 2007.
- 173) Fast dissolving tablets - Current development and technologies, OGD, USFDA, Rockville, MD, April 23, 2007.
- 174) Overview of polymers used in controlled release, China International Pharmaceutical Technologies Conference 2007, Shanghai, China, May 10-14, 2007.
- 175) Nanomedicine: Evolution, revolution, and transformation, Kazakh National University, Almaty, Republic of Kazakhstan, June 13, 2007.
- 176) Polymers used in controlled drug delivery, Kazakh National University, Almaty, Republic of Kazakhstan, June 14, 2007.

- 177) Polymers in nanotechnology, Kazakh National University, Almaty, Republic of Kazakhstan, June 15, 2007.
- 178) Nanotechnologies in drug delivery, Chungnam National University, Daejeon, South Korea, August 14, 2007.
- 179) Orally disintegrating tablets: Determination of disintegration time, OGD, USFDA, Rockville, MD, August 21, 2007.
- 180) Imaging studies of paclitaxel release from drug-eluting stents. The University of Arizona, Department of Aerospace and Mechanical Engineering, Tucson, AZ, November 8, 2007.
- 181) Hydrotropic polymer micelle for delivery of poorly water-soluble drugs, The 10th European Symposium on Controlled Drug Delivery, Noordwijk aan Zee, The Netherlands, April 2-4, 2008.
- 182) Hydrotropic micelles for poorly water-soluble drugs, Macromolecular Chemistry Symposia, 101th National Meeting of the Korean Chemical Society, Seoul, Korea, April 17, 2008.
- 183) Animal models in drug delivery: Indispensables, limitations and alternatives, The 35th CRS Annual Meeting, New York, NY, July 14, 2008.
- 184) Drug-eluting stents: What need to be done, Kyungpook National University Medical School, Daegu, Korea, September 2, 2008.
- 185) Bioefficacy studies in drug delivery: Animal models and alternatives, The 2008 KCRS Annual Conference: Research Networking for Future Therapy, Jeju Island, Korea, September 4, 2008.
- 186) Macro issues with nano/micro particles for drug delivery, Center for Nanoscale Science and Technology, University of Illinois, Urbana-Champaign, October 1, 2008.
- 187) Hydrotrophic polymer micelles for delivery of poorly soluble drugs, University of Pennsylvania School of Medicine, October 15, 2008.
- 188) Drug delivery systems: Macro issues of nano/micro formulations, University of Wisconsin, School of Pharmacy, Louis W. Busse Lecture Series, November 13, 2008.
- 189) Drug-eluting stents: What now? University of Wisconsin, School of Pharmacy, Louis W. Busse Lecture Series, November 14, 2008.
- 190) Long-term protein delivery: Challenges and opportunities, The 2nd International Quadruple Research Network Symposium - Protein, Gene, Cell Delivery, Hanyang University, Seoul, Korea, December 5, 2008.
- 191) Nanotechnology in drug delivery: Issues & possibilities, Korea Research Institute of Chemical Technology, Taejeon, Korea, December 8, 2008.
- 192) Nano/micro particles with predefined size and shape, 14th International Symposium on Recent Advances in Drug Delivery Systems, Salt Lake City, UT, Feb. 15-18, 2009.
- 193) Delivery of poorly water-soluble drugs: Hydrotropic solubilization and nano/micro-particles, Pfizer, Groton, CT, March 6, 2009.
- 194) Practical nanotechnology and microfabrication for drug delivery, 2009 International Symposium of the Intelligent Drug Delivery System, Seoul, Korea, April 29, 2009.
- 195) Aquatemplate method for microparticulate drug delivery systems, Sungkyunkwan University, College of Engineering, Suwon, Korea, May 1, 2009.
- 196) Polymers in drug delivery systems & gastric retention devices, Astellas Pharma, Shizuoka, Japan, May 22, 2009.
- 197) Drug delivery systems: Basic research and product development, Academy of Pharmaceutical Science and Technology, Japan (APSTJ), Shizuoka, Japan, May 23, 2009.

- 198) Drug-eluting stents: The future trend, the 7th Asia 3 (China-Japan-Korea) Foresight Symposium on Gene Therapy and Biomaterials, Seoul, Korea, May 26, 2009.
- 199) Oral delivery of macromolecular drugs: Limitations and possibilities, 2009 World Class University (WCU) Symposium on Drug Delivery and Bioimaging, Daegu, Korea, May 28, 2009.
- 200) Novel Drug Delivery Systems for Translational Research, Cardiovascular Innovation Seminar Series, Medtronic Cardiovascular, Santa Rosa, CA, August 12, 2009.
- 201) Nanotechnology in drug delivery, Korea Advanced Institute of Science and Technology, Daejeon, Korea, September 1, 2009.
- 202) Nano/micro fabrication for drug delivery systems, Green Cross Pharma, Seoul, Korea, September 2, 2009.
- 203) Nanotechnology in drug delivery, POSTECH, Pohang, Korea, September 3, 2009.
- 204) Macro issue with nano/micro particles in drug delivery, 2009 International Symposium on Crystal Engineering & Drug Delivery System, Tianjin, China, September 6, 2009.
- 205) Advances in drug delivery based on nanotechnology, Ajou University, Suwon, Korea, September 10, 2009.
- 206) Nanotechnology applications for drug delivery, 12th Annual International Conference on Drug Metabolism/Applied Pharmacokinetics, Merrimac, WI, September 17, 2009.
- 207) A new nanofabrication method designed for scale-up production, 7th International Nanomedicine and Drug Delivery Symposium, Indianapolis, IN, October 5-6, 2009.
- 208) Advances in nanofabrication in drug delivery, Advanced Polymeric Materials and Technology Symposium (APMT 2010), Jeju, Korea, January 24-27, 2010.
- 209) The hydrogel template method for nanofabrication of drug delivery particles, The American Society of Mechanical Engineers (ASME)/ the First Global Congress on NanoEngineering for Medicine and Biology (NEMB): Advancing Health Care through Nanoengineering and Computing, Houston, TX, February 8, 2010.
- 210) Nanofabrication of microstructures for drug delivery using the hydrogel template method, Macromolecular Science and Engineering, University of Michigan, Ann Arbor, February 16, 2010.
- 211) Long-term drug delivery using microfabricated particles, Advanced Technologies and Regenerative Medicine (Johnson & Johnson), Somerville, NJ, April 5, 2010.
- 212) A (toy) story of drug delivery systems, Sigma Xi Purdue Chapter, West Lafayette, IN, April 14, 2010.
- 213) Microfabricated particles for controlled drug delivery, Zhejiang University, Department of Chemical and Biochemical Engineering, Hangzhou, China, April 20, 2010.
- 214) Microfabricated particles for controlled drug delivery, Peking University, Department of Polymer Sciences & Engineering, Beijing, China, April 23, 2010.
- 215) Development of large dose FDT formulations & microparticulate depot injectables, CKD Pharmaceutical, Seoul, Korea, April 26, 2010.
- 216) Targeted drug delivery: Essential for further advances in drug delivery, The 9th China-Japan-Korea Foresight Joint Symposium on Gene Delivery and the International Workshop on Biomaterials 2010, Changchun, Jinlin, China, June 21, 2010.
- 217) Drug delivery systems: oral and parenteral formulations, AmorePacific, Suwon, Korea, June 24, 2010.
- 218) Fabrication of long-term release risperidone-PLGA microsystems, Samyang Corp., Daejeon, Korea, June 25, 2010.

- 219) Drug-eluting stents with controllable elution kinetics, SIRIC International Symposium 2010, Stent development: Present and Future, Severance Hospital, Seoul, Korea, July 2, 2010.
- 220) Where have all the smart hydrogels gone? The Annual Controlled Release Society Meeting, Portland, OR, July 14, 2010.
- 221) A new microfabrication method for delivery of various types of drugs, The 19th Shizuoka DDS Conference, Shizuoka, Japan, September 4, 2010.
- 222) Microstructures for drug delivery using the hydrogel template method, University of Tokyo, Tokyo, Japan, September 6, 2010.
- 223) Targeted drug delivery: Expected targeting and true targeting, Tokyo Women's University, Tokyo, Japan, September 7, 2010.
- 224) Wild wild world of drug delivery systems: From macro to nano, Tokyo Institute of Technology, Tokyo, Japan, September 9, 2010.
- 225) Targeted drug delivery: The next advances to be made, The 5th Global COE International Symposium on Frontier in Biomaterials Science and Technology for Regenerative Medicine and Gene/Drug Delivery, Tokyo Institute of Technology, Tokyo, Japan, September 10, 2010.
- 226) Drug targeting: Myth, reality, and possibility, Symposium on Innovative Polymers for Controlled Delivery (SIPCD 2010), Suzhou, China, September 15, 2010.
- 227) Nano-Med: Recent advances in nanotechnology for drug delivery, Suzhou Institute of Nano-Tech and Nano-Bionics, Chinese Academy of Sciences, Suzhou, China, September 16, 2010.
- 228) Long-term protein delivery: Challenges & opportunities, Genentech, South San Francisco, CA, December 2, 2010.
- 229) Recent advances in hydrogel drug delivery for biotherapeutics and major hurdles to commercialization, 46th Annual Pharmaceutical Technologies Arden Conference: Pharmaceutical Development of Biologics: Fundamentals, Challenges, and Recent Advances, The Thayer Hotel, West Point, NY, March 8, 2011.
- 230) Controlled Drug Delivery: Clinically Useful Formulation & Commercial Success, CKD Research Institute, Chonan, Korea, April 27, 2011.
- 231) Drug delivery: New directions in the new decade, The 10th China-Japan-Korea Foresight Joint Symposium on Gene Delivery and International Symposium on Biomaterials 2011, Gulin, Guangxi, China, May 31, 2011.
- 232) Controlled drug delivery technologies for clinically useful practical formulations, Changchun Institute of Applied Chemistry, Changchun, China, June 3, 2011.
- 233) Barriers to overcome for targeted drug delivery to tumors, Drug Delivery and Cancer: Challenges and New Directions for Cancer Therapy, West Lafayette, IN October 10, 2011.
- 234) The 10Xer's way toward theragnosis, Korea Institute of Science and Technology, Seoul, Korea, November 24, 2011.
- 235) How smart is a smart hydrogel? Yeongnam University, Daegu, Korea, November 25, 2011.
- 236) Infinite future of undergraduate students, Korea University, School of Pharmacy, Jochiwon, Korea, November 28, 2011.
- 237) Targeted drug delivery: myth, reality, & possibility, Department of Pharmaceutical Sciences, University of Tennessee Health Science Center, Memphis, TN, December 12, 2011.
- 238) Controlled drug delivery: The third generation, International Symposium on Past, Present and Future of Molecular Pharmacokinetics, Hitotsubashi Hall, Tokyo, Japan, January 18, 2012.

- 239) Targeted drug delivery: myth, reality, & possibility, Department of Mechanical Engineering, University of Minnesota, Minneapolis, MN, March 28, 2012.
- 240) Nanoadvances in nanotechnology-based drug delivery, KAIST, Daejeon, Korea, April 16, 2012.
- 241) Drug delivery systems for the new decades: Balance between “*iNew*” and “Me-too” approaches. National Tsing Hua University, Hsinchu, Taiwan, April 26, 2012.
- 242) Publication of papers for Journal of Controlled Release. Changchun Institute of Applied Chemistry, Chinese Academy of Sciences, Changchun, China, June 1, 2012.
- 243) How to write good papers for JCR. West China School of Pharmacy, Sichuan University, Chengdu, China, June 2, 2012.
- 244) The 3rd Generation drug delivery systems: Issues to Resolve. The 9th World Biomaterials Congress, Chengdu, China, June 3, 2012.
- 245) Politicians, Athletes, Scientists, and *iCRS*. The 39th Annual Meeting of the Controlled Release Society, Quebec, Canada, July 17, 2012.
- 246) Drug Delivery Systems for the New Decade: Balance between “*iNew*” and “Me-too” Approaches, the 15th International Biotechnology Symposium, Daegu, Korea, September 17, 2012.
- 247) The 3rd Generation drug delivery systems: Back to Basics, the 3rd Asymchem Pharmaceutical CMC 2012, Tianjin, China, September 21, 2012.
- 248) The 10X Research on Drug Delivery, Sungkyunkwan University, Korea, September 24, 2012.
- 249) The 3rd generation drug delivery systems: Improvement to make, Peking University, Beijing, China, December 1, 2012.
- 250) Controlled Drug Delivery Systems, CoSci-Med, Harbin, China, December 2, 2012.
- 251) Controlled drug delivery systems for the new decade, Heilongjiang University, Harbin, China, December 3, 2012.
- 252) Oral controlled drug delivery systems, Symposium on New Technology Seminar on Extended and Controlled Release Oral Solid Dosage (VIII), Guangzhou, China, December 4, 2012.
- 253) Controlled release formulations for generics, The 3rd International Forum for Generics, Nanchang, China, December 5-6, 2012.
- 254) Anti-retroviral delivery systems: New directions in the new decades, NIH National Institute of Allergy and Infectious Diseases, Division of AIDS, Prevention Sciences Program and The Bill and Melinda Gates Foundation. Think Tank on Drug Delivery Systems for HIV Prevention, Washington, DC, February 22, 2013.
- 255) Controlled drug delivery systems: The third generation, International Conference on Biomaterials Science, Tsukuba, Japan, March 20-22, 2013.
- 256) Targeted drug delivery: Insights by Professor You Han Bae, Joint Symposium of the 5th Utah-Inha DDS Research Center Symposium and the 7th International Symposium on Intelligent DDS, Incheon, Korea, May 23-24, 2013.
- 257) The missing components of current drug delivery systems and new approaches, The 4th International Advanced Biomaterials Symposium Changchun, China, September 28-30, 2013.
- 258) Facing the truth about nanotechnology in drug delivery, Dongguk University, Pharmacy School in Ilsan. October 2, 2013.
- 259) Controlled drug delivery: new technologies required for the next generation, Symposium on Perspectives on the Future of Drug Delivery Systems, Beijing, China, November 22, 2013.

- 260) Controlled drug delivery: Challenges and Opportunities, Youbo Pharmaceuticals, Mudanjiang, China. March 10, 2014.
- 261) The 3rd generation drug delivery systems: Future back, the 8th International Symposium on Intelligent Drug Delivery System, Seoul, Korea, April 24, 2014.
- 262) Create your own future, Korea University, Jochiwon, Korea, May 28, 2014.
- 263) Controlled drug delivery: Historical perspective for the future, Ajou University, Suwon, Korea. November 3, 2014.
- 264) Virtual human, KIST, Seoul, Korea, November 4, 2014.
- 265) From pills to nanoparticles: The 10X progress in drug delivery research, Korean-American Society in Biotech and Pharmaceuticals (KASBP), Morristown, NJ, November 7, 2014.
- 266) 30 Years of Research on Drug Delivery: A Personal Reflection, Purdue University Faculty Careers Colloquium, West Lafayette, IN, February 20, 2015.
- 267) Vacuum SpinSwiper for microfabrication of PLGA microparticles, Sungkyunkwan University, Suwon, Korea, March 24, 2015.
- 268) Controlled drug delivery: Historical perspective for the next generation, Pharmaceutical Society Japan, Kobe, Japan, March 28, 2015.
- 269) Drug delivery technologies for the future: Thinking in new boxes, Ashland Inc. Distinguished Lecturer at the University of Kentucky, April 27 2015.
- 270) Controlled drug delivery systems: Needs for accelerated evolution, the Canadian Biomaterials Society, Toronto, Canada, May 29, 2015.
- 271) Drug delivery of the future: Chasing the invisible gorilla, The 1st Annual International Symposium on Bio-Therapeutics Delivery, Seoul, Korea, September 14, 2015.
- 272) Sustained depot formulations for parenteral applications, CJ HealthCare, Icheon-si, Gyeonggi-do, Korea, September 18, 2015.
- 273) PLGA microparticle formulations for long-term drug delivery, Korea University, Jochiwon, Korea, September 21, 2015.
- 274) Drug delivery of the future: Chasing the invisible gorilla, Lilly/Purdue Technology Day, Eli Lilly, Indianapolis, IN, October 5, 2015.
- 275) Controlled Drug Delivery: Historical perspective for the next generation, Sungkyunkwan University, College of Engineering and College of Pharmacy, Suwon, Korea, November 19, 2015.
- 276) Controlled Drug Delivery: Historical perspective for the future, The Chinese University of Hong Kong, College of Pharmacy, Sha Tin, Hong Kong, March 16, 2016.
- 277) Lessons learned from Dr. Tsuneji Nagai for the future of drug delivery, the 30th Anniversary Symposium of The Nagai Foundation Tokyo: Link to the Past and Bridge to the Future, Tokyo, Japan, July 7, 2016.
- 278) Drug Delivery Systems: Achieving Accelerated Evolution, the 10th Israel Controlled Release Society Symposium, Maalot, Israel, September 16, 2016.
- 279) Drug Delivery Systems: Accelerated Evolution for the Future, Allan S. Hoffman Lecture, University of Washington, Seattle, WA, October 10, 2016.
- 280) Drug delivery systems: Past successes and future possibilities, the 28th Korean Academy of Science & Technology Symposium: Young Scientists in Drug Delivery- Redirecting the Research Field, KIST, Seoul, Korea, December 7, 2016.

- 281) PLGA microparticles; Challenges in peptide and protein delivery, Eli Lilly and Company, Indianapolis, IN, March 9, 2017.
- 282) Center for drug abuse intervention and treatment, National Institute of Drug Abuse, Baltimore, MD, April 7, 2017.
- 283) The drug delivery field at the inflection point, IDDS-GiRC Joint Symposium, Seoul, Korea, May 25, 2017.
- 284) The drug delivery field at the inflection point: Why we need to change, University of Utah, Salt Lake City, UT, August 28, 2017.
- 285) Characterizations of PLGA polymers, FDA Public Workshop on Demonstrating Equivalence of Generic Complex Drug Substances and Formulations: Advances in Characterization and In Vitro Testing, Silver Spring, MD, October 6, 2017.
- 286) The drug delivery field at the tipping point, Korea University, Jochiwon, Korea, October 20, 2017.
- 287) Drug delivery systems: Accelerated evolution for the future, Monash University, Melbourne, Australia, November 17, 2017.
- 288) Preparing manuscripts and patents, University of Auckland, Auckland, New Zealand, November 21, 2017.
- 289) Bioefficacy and toxicity studies in drug delivery: Animal models & alternatives, in New Zealand-Australia CRS 2017 Joint Workshop on Recent Trends in In-vitro, Ex-vivo and In-vivo Models in Bioactive Delivery, November 22, 2017.
- 290) Drug delivery systems: Past successes and future possibilities, University of Otago, Dunedin, New Zealand, November 24, 2017.
- 291) Preparing manuscripts for Journal of Controlled Release, University of Otago, Dunedin, New Zealand, November 24, 2017.
- 292) The drug delivery field at the inflection point: Time for new thinking, University of Auckland, Auckland, New Zealand, November 27, 2017.
- 293) Role of drug delivery in drug discovery, University of Auckland, Auckland, New Zealand, November 28, 2017.
- 294) The drug delivery field at the inflection point: Time to change for the future, University of Southern California, Los Angeles, CA, February 24, 2018.
- 295) The drug delivery field at the inflection point, The KAST 13th Frontier Scientist Workshop: Future Trends of Biomaterials, University of Utah, Salt Lake City, UT, June 18-19, 2018.
- 296) A long walk to PLGA. The 2018 Annual Meeting of Controlled Release Society, New York, NY, July 22, 2018.
- 297) The future of the drug delivery field: Lessons learned from Professor Diane Burgess, The Interface between Science and Education. A Celebration of Professor Diane J. Burgess' 60th Birthday, Storrs, CT, August 18, 2018.
- 298) PLGA microparticles: Very well-known but unexplored formulations, Fifth Symposium of Innovative Polymers for Controlled Delivery, Suzhou, China, September 15, 2018.
- 299) The drug delivery field at the inflection point: Time to think differently, West China School of Pharmacy, Sichuan University, Chengdu, China, November 5, 2018.
- 300) The drug delivery field at the inflection point: Time to think differently, Engineering Research Center in Biomaterials, Sichuan University, Chengdu, China, November 6, 2018. West China School of Pharmacy, Sichuan University, Chengdu, China, November 6, 2018.

- 301) Create your own future, West China School of Pharmacy, Sichuan University, Chengdu, China, November 6, 2018.
- 302) One life, one chance, Purdue Korean Faculty Association, West Lafayette, IN, December 14, 2018.
- 303) The future of the drug delivery field: time to make real changes, 17th International Symposium on Advances in Technology and Business Potential of New Drug Delivery Systems, Mumbai, India, February 2, 2019.
- 304) Characterization considerations for complex generics containing PLGA, Section "Advancing Pharmaceutical Science in Generic Industry-1), 33rd International Forum Processing Analysis & Control (IFPAC-2019), North Bethesda, MD, March 4, 2019.
- 305) Drug delivery: Collective progress beyond nanohorizon, Nanomedicine Symposium, Aurora, CO, April 26, 2019.
- 306) An assessment of the current and likely impact of the science of crossing biological barriers on medicine, Keystone Symposium on Delivering Therapeutics across Biological Barriers, Dublin, Ireland, May 9, 2019.
- 307) PLGA: Very well-known but unknown polymers, Helmholtz-Zentrum Geesthacht. Centre for Materials and Coastal Research, Berlin, Germany, May 14, 2019.
- 308) Nanoprogess in nanomedicine: Mission NanoAccomplished, 2019 Controlled Release Society (CRS) Annual Meeting, Debate on Nanotechnology: Big progress vs nano progress, Velencia, Spain, July 22, 2019.
- 309) Importance of polymer characterization in transdermal and cosmetic formulations, Fifth Conference of transdermal drug delivery in world federation of Chinese medicine societies, Nanjing. China, August 17, 2019.
- 310) One life, one chance: Create your own future, China Pharmaceutical University, Nanjing, China, August 19, 2019.
- 311) PLGA formulations: Understanding the complexicity of the PLGA assay, Chinese American Society of Nanomedicine and Nanotechnology, Hangzhou, China, August 20, 2019.
- 312) Kinam Park and Fernanda Ogochi: How to get published in Journal of Controlled Release: Perspectives of the editor and the publisher, Chinese American Society of Nanomedicine and Nanotechnology, Hangzhou, China, August 20, 2019.
- 313) Characterization of complex PLGA formulations, FDA, Silverspring, MD, September 12, 2019.
- 314) Kinam Park and Fernanda Ogochi: Writing research articles, West China School of Pharmacy, Chengdu, China, September 19, 2019.
- 315) Reshapable hydrogels for soft tissue expansion, Engineering Research Center in Biomaterials, Sichuan University, Chengdu, China, September 19, 2019.
- 316) Drug Delivery: What Do We Do Now? The 1st Asian Young Investigator Symposium on Pharmaceutical Science and Technology, Chengdu, China, September 20, 2019.
- 317) Professor Doo Sung Lee: A pioneer in environment-sensitive polymers, Polymer Society of Korea, Seogwipo, Jeju, Korea, October 10, 2019.
- 318) Stand firm on the goal of your life, College of Pharmacy, Seoul National University, Seoul, Korea, October 11, 2019.
- 319) Time for Korean pharmaceutical science to move ahead of the world, Pharmaceutical Society of Korea, Yeosu, Korea, October 14, 2019.

Awards by Graduate students

- 1) Yoon Yeo: 2002 CRS-3M Drug Delivery Systems Graduate Student Outstanding Research Award in Drug Delivery (Controlled Release Society, July, 2003)
- 2) Yong Qiu: AAPS Outstanding Graduate Student Research Award in Pharmaceutical Technologies (American Association of Pharmaceutical Scientists, October 2003)
- 3) Yoon Yeo: AAPS Outstanding Graduate Student Research Award in Pharmaceutical Technologies (American Association of Pharmaceutical Scientists, November 2004)
- 4) Drug Delivery Special Interest Group Outstanding Contribution to the Society for Biomaterials (Eunah Kang: Society for Biomaterials 2007)

Reviewer for Scientific Organizations

- 1) Reviewer for the Petroleum Research Fund of the American Chemical Society (1991, 1992, 1994, 1997, 2000).
- 2) Special reviewer for the Medical Research Council of Canada (1991, 1996), and the National Sciences and Engineering Research Council of Canada (1998, 2001).
- 3) Reviewer for the U.S. Civilian Research & Development Foundation. Regional Experimental Support Center Program 2000-2001 (2000).
- 4) Reviewer for the Maryland Sea Grant College of the National Office's Sea Grant Technology Program (2002)
- 5) Reviewer for Canadian Institute of Health Research (2003)
- 6) Reviewer for Connecticut Innovations (2005)
- 7) Reviewer for the Netherlands Organisation for Scientific Research (2009)
- 8) Reviewer for the BMM/CTMM/TIPharma, the Netherlands (2009)
- 9) Reviewer for Lister Institute Research Prizes, United Kingdom (2012)

Reviewer for Academic Departments

- 1) University of Minnesota, Department of Pharmaceutics, 1998
- 2) University of Utah, Department Pharmaceutics and Pharmaceutical Chemistry, 2004.
- 3) School of Pharmacy at Queen's University Belfast, Belfast, United Kingdom, 2011.

Short Course Instructor

- 1) Peppas, N.A. and Park, K.: Hydrogels in Biomedical and Pharmaceutical Applications, held at Indianapolis, IN, on April 24-26, 1991.
- 2) Peppas, N.A. and Park, K.: Hydrogels in Biomedical and Pharmaceutical Applications, held at Purdue University, West Lafayette, IN, on May 5-7, 1992.

National and International Committee Member

- 1) Program Planning Committee for the American Association of Pharmaceutical Scientists (AAPS) Meeting (Fall, 1987).
- 2) Scientific Program Committee for the 1990 Controlled Release Society Meeting (July, 1990).

- 3) Abstract review for the Pharmaceutics and Drug Delivery Section of the American Association of Pharmaceutical Scientists (AAPS) Meeting (Fall, 1991).
- 4) Program Planning Committee for the Controlled Release Society Symposium to be held in Korea (1992).
- 5) Controlled Release Society Award Committee in Outstanding Pharm/Ag-Vet Section (1992-1993).
- 6) Controlled Release Society Award Committee in Graduate Student Research Awards & Young Investigator Research Award (1993-1996)
- 7) Controlled Release Society Nominations Committee (1993-1996).
- 8) Controlled Release Society Committee in Ag/Vet Development (1993-1996).
- 9) Abstract review for the Protein Adsorption Section of the Society for Biomaterials Meeting (1993).
- 10) Task Force on Global Membership Network of the Controlled Release Society (1993).
- 11) Controlled Release Society Award Committee in Outstanding Pharm/Ag-Vet Section (1993-1994).
- 12) Abstract review committee for the 20th Annual Meeting of the Society for Biomaterials (held in Boston, April 5-9, 1994).
- 13) Advisory Board of the Molecular Modeling Conference (1994)
- 14) Scientific Program Committee for the 1996 Controlled Release Society Meeting (1994).
- 15) Chairman of the Global Network Team of the Controlled Release Society (1994-1995).
- 16) Advisory Panel on Polymeric Excipients, USP (1995-1999)
- 17) Chairman of the Global Network Committee of the Controlled Release Society (1995-1996).
- 18) Chairman of the Fellow selection committee of the Pharmaceutics and Drug Delivery (PDD) section of the American Association of Pharmaceutical Scientists (AAPS) (1996-1997).
- 19) ACS Books Advisory Board (1997-2000)
- 20) Advisory Panel on Current Drugs (1997-1999)
- 21) Scientific Advisory Board, International Symposium on the Frontiers in Biomedical Polymers Applications (2000-2001)
- 22) Scientific Advisory Board, International Symposium on Recent Advances in Drug Delivery Systems (2000-2001)
- 23) Advisory Panel on Excipients: Substance and Characterization Expert Committee, USP (2000-2005)
- 24) Scientific Program Committee of the 2nd Pharmaceutical Sciences World Congress (PSWC2004) (2001-2004).
- 25) Workshop Committee for the Controlled Release Society's Workshop on Optimization of Quality and Performance Attributes of Controlled Release Products, Seoul, Korea (2001-2002)
- 26) International Advisory Committee of the First International Conference on Medical Implants Bethesda, MD (July 25-28, 2003)
- 27) Scientific Advisory Board, Third International Nanomedicine and Drug Delivery Symposium (2005)
- 28) Scientific Advisory Board, European Symposium on Controlled Drug Delivery (2006-)
- 29) Scientific Advisory Board, China International Pharmaceutical Technologies Conference 2007 (2006-)
- 30) Scientific Organizing Committee for Micro 2007, The 16th International Symposium on Microencapsulation (2007)

- 31) International Advisory Board, the 3rd International Conference on Smart Materials, Structures and Systems (2007-2008)
- 32) International Organizing Committee, Symposium on Innovative Polymers for Controlled Delivery, Suzhou, China, September 14-17, 2010.
- 33) Nominations Committee for Controlled Release Society, 2010-2011.
- 34) Symposium Co-Chairman, 4th International Advanced Biomaterials Symposium 2013, September 28-October 2, 2013, Changchun, China.
- 35) International Committee of the Athens Congress on Computational-Experimental, Scientific-Regulatory Advances in Drug Discovery, Formulation Strategies, Drug Delivery, ADMET for Small Molecules (Generics) and Biotechnological (Biosimilar) Drugs, Athens, Greece, May 30-June 1, 2015.
- 36) The Annual Meeting Programme Committee for the Controlled Release Society conference in 2015, Edinburgh, Scotland, July 25-29, 2015.
- 37) The nominating committee of the Controlled Release Society, 2016-2017.
- 38) The nominating committee of the Controlled Release Society, 2017-2018.

Meeting Organizer

- 1) The 1989 Scanning Microscopy Meeting on "Colloidal gold: quantitative labeling and new applications," held in Salt Lake City, UT, on May 1-5, 1989.
Co-organizer: Dr. Ralph Albrecht, University of Wisconsin.
- 2) The 1994 ACS National Meeting on "First International Symposium on Biorelated Polymers," sponsored by the Division of Polymer Chemistry, held in Washington, D.C., on August 21-25, 1994.
Co-organizers: Dr. Raphael Ottenbrite, Virginia Commonwealth University, and Dr. Samuel Huang, University of Connecticut.
- 3) Organizer for the workshops on "Particulate Drug Delivery Systems" and "Development of Hydrogel dosage forms" of the 1996 Controlled Release Society Meeting in Kyoto, Japan on July 11-12, 1996.
- 4) A member of the organizing committee for the First Asian International Symposium on Polymeric Biomaterials Science, held in Ishikawa, Japan on May 14-16, 1997.
- 5) KSP and CRS Joint Symposium on Recent Advances in Drug Delivery and Biomaterials, held in Seoul, Korea on September 24-26, 1997.
Program co-chairman: Seo Young Jeong
- 6) The 1998 Controlled Release Society Meeting, held in Las Vegas on June 22-24, 1998.
Program co-chairman: Russell Potts.
- 7) Program Chairman for "Recent Advances in Controlled Drug Delivery," in The WorldPharm98, held in Philadelphia, PA on September 22-24, 1998.
- 8) American Chemical Society Symposium on "Drug Delivery in the 21st Century" sponsored by the Division of Polymer Chemistry, held in Anaheim, CA on March 21-25, 1999.
Co-organizer: Randall Mersny.
- 9) The Controlled Release Society Winter Symposia and 11th International Symposium & Exposition on Recent Advances in Drug Delivery Systems, held in Salt Lake City, UT on March 3-6, 2003.
Co-organizers: Jindrich Kopecek, James Anderson, Martyn Davies, Sung Wan Kim.

10) The workshops on "CMC Regulatory Issues for Controlled Release Parenterals," of the 2006 Controlled Release Society Meeting in Vienna, Austria on July 22, 2006. Co-organizer: Diane Burgess.

11) International Symposium on Recent Advances in Drug Delivery, held in Salt Lake City, UT on February 26-28, 2007.

Co-Chairmen: David Granger and You Han Bae.

12) Program Chairman of the Annual Meeting of the Society for Biomaterials held in Chicago, IL, 2007.

13) Program Chair for the pharma themes (Chemistry for Health: Catalyzing Translational Research) for the ACS Annual Meeting, held in Philadelphia, PA, in August 2008.

14) International Symposium on Recent Advances in Drug Delivery, held in Salt Lake City, UT on February 15-17, 2009.

Co-Chairmen: David Granger and You Han Bae.

15) Drug Delivery and Cancer: Challenges and New Directions for Cancer Therapy, held in West Lafayette, IN on October 10-11, 2011,

Co-Chairmen: Alex Wei, Donald Berstrom, and Kinam Park.

16) Chair, the Annual Meeting Programme Committee for the Controlled Release Society conference in 2016, Seattle, WA, USA, July 16-20, 2016.

17) Co-Chair, Randy Mrsny, Kinam Park, Isabelle Aubert, and Cornell Stamoran, Chairs. Non-invasive Delivery of Macromolecules Conference 2017, San Diego, CA, USA, February 21-24, 2017.

Chairman at Meetings

1) Chairman of a section on "Artificial Surfaces" at the 1986 Scanning Electron Microscopy Meeting, held in New Orleans, LA, on May 5-9, 1986.

2) Chairman of a section on "Bioadhesives" at the 14th International Symposium on Controlled Release of Bioactive Materials, held in Toronto, Canada, on August 2-5, 1987.

3) Chairman of a session on "Ancillary and Correlative Techniques II - Labeling," at The 7th Pfefferkorn Conference on Science of Biological Specimen Preparation, held in Guildford, England, on September 12-16, 1988.

4) Chairman of a section on "Biopharm I" at the 17th International Symposium on Controlled Release of Bioactive Materials, held in Reno, NV, on July 22-25, 1990.

5) Chairman of a session on "Vascular Prosthesis" at the 38th Annual Meeting of American Society for Artificial Internal Organs, held in Nashville, TN, on May 7-9, 1992.

6) Chairman of a session on "Fourth International Symposium on Polymeric Drugs and Drug Delivery Systems" at the 204th ACS National Meeting, held in Washington, D.C., on August 24, 1992.

7) Co-Chairman of a session on "Polymers of Biological and Biomedical Significance" at the 204th ACS National Meeting, held in Washington, D.C., on August 26, 1992.

8) Co-Chairman of a session on "Bioadhesives" at the AIChE Annual Meeting, held in Miami Beach, FL, on November 4, 1992.

9) Co-Chairman of a session on "Mathematical and Computer Modeling" at the 22nd International Symposium on Controlled Release of Bioactive Materials, held in Seattle, WA, on July 30-August 2, 1995.

- 10) Co-Chairman of a session on "Biomaterials and Drug Delivery" at the 42nd Annual Conference of American Society for Artificial Internal Organs, held in Washington, D.C., on May 3, 1996.
- 11) Chairman of a session on "Transdermal Products Development" at the Third International Symposium on Biomaterials and Drug Delivery Systems, held in Taejeon, Korea, on July 4-5, 1996.
- 12) Co-Chairman of a section on "Agriculture/Veterinary Applications 1 - Session II" at the 23rd International Symposium on Controlled Release of Bioactive Materials, held in Kyoto, Japan, on July 7-10, 1996.
- 13) Chairman of a session on "Biorelated Polymers: Advances in Polymeric Drugs and Drug Design" at the 212th American Chemical Society National Meeting, held in Orlando, FL, on August 25-29, 1996.
- 14) Chairman of a session on "Polymer Design I" at the 8th International Symposium on Recent Advances in Drug Delivery Systems, held in Salt Lake City, UT, on February 24-27, 1997.
- 15) Chairman of 7 sessions of "Recent Advances in Controlled Drug Delivery" at The WorldPharm98, held in Philadelphia, PA, on September 22-24, 1998.
- 16) Chairman of a session on "Polymeric Carriers" at the 8th International Symposium on Recent Advances in Drug Delivery Systems, held in Salt Lake City, UT, on February 19-22, 2001.
- 17) Chairman of a session on "Issues in Protein Microencapsulation" at the AAPS Conference on Advances in Pharmaceutical Processing, held in Parsippany, NJ, on June 19-20, 2003.
- 18) Co-Chairman of a session on "Colloidal Drug Carriers" at the 32nd Annual Meeting of the Controlled Release Society, held in Miami, FL, on June 18-22, 2005.
- 19) Co-Chairman of a session on "Industrial Session and Roundtable: From Bench to Bedside" at the NanoDDS 10, held in Omaha, NE, on Oct. 3-5, 2010.
- 20) Co-Chairman of a session on "New Concepts in Polymer Gene/drug/RNAi Delivery Systems" (SO51-16.2) at the 9th World Biomaterials Congress, held in Chengdu, China on June 3, 2012.
- 21) Co-Chairman of a session on "Preparation and Biomedical Applications of Bioactive Polymer Materials" (SO52-33 & SO64-33) at the 9th World Biomaterials Congress, held in Chengdu, China on June 3, 2012.
- 22) Chairman of a Plenary Session by Dr. Kenzo Takada at the Controlled Release Society Meeting in Honolulu, Hawaii, July 22, 2013.
- 23) Co-Chairman of a session on Parenteral Sustained Release Drug Delivery at the Controlled Release Society Meeting in Honolulu, Hawaii, July 22, 2013.
- 24) Chairman of a session on Blood-Brain Barrier at the Non-invasive Delivery of Macromolecules Conference 2017, San Diego, CA, USA, February 22, 2017.
- 25) Co-chairman of Session 4, Fifth Symposium of Innovative Polymers for Controlled Delivery, Suzhou, China, September 16, 2018.

Teaching Responsibility

- 1) IPPH 363: Basic Pharmaceutics II: Controlled release drug delivery systems (1986-2006, 2009)
- 2) IPPH 581: Disperse Systems: physicochemical and thermodynamic properties of polymers used in the pharmaceutical area. (1986-1996)
- 3) IPPH 669: Rate Processes: Rate processes occurring in biological systems. (1987-1995)
- 4) BMS 517A: Tissue engineering (on biomaterials and drug delivery) (2000)
- 5) ChE 697C: Biomaterials Science (on biomaterials and drug delivery) (2001)

- 6) IPPH 690W: (BME695K): Polymers in Pharmaceutical and Biomedical Systems (2000 - 2014)
- 7) ChE 461: Biomedical Engineering (2008 - 2018)
- 8) Engr 103: Introduction to Engineering Practice (2008 - 2018)
- 9) BME 290: Frontiers in Biomedical Engineering (2010)
- 10) IPPH 100: Orientation Course (2017 - 2018)
- 11) BME 295/299: BME Research Scholars I (2017)
- 12) BME 489/490: BME Senior Design (2018)
- 13) BME 695K: Polymers in Biomedical and Pharmaceutical Systems (2016 -)

Thesis Supervision

- 1) Donghao Robert Lu - "Protein behavior at the solid-liquid interface."
He graduated with a Ph.D. degree in August 1990 to become Assistant Professor at Idaho University.
- 2) Fei-Wen Mao - "Polymer grafting and steric repulsion."
She graduated with a M.S. degree in April, 1990.
- 3) Waleed S.W. Shalaby - "Enzyme-digestible hydrogels for oral drug delivery"
He graduated with a Ph.D. degree in July 1992. He continued his education at the School of Medicine of the University of South Carolina and obtained his M.D. degree in 1996.
- 4) Mansoor M. Amiji - "Steric repulsion by PEO/PPO/PEO block copolymers"
He graduated with a Ph.D. degree in August 1992 to become Assistant Professor at School of Pharmacy, Northeastern University.
- 5) Kalpana R. Kamath - "Albumin grafting by γ -irradiation"
She graduated with a Ph.D. degree in August 1993 to become Assistant Professor at School of Pharmacy, University of South Dakota.
- 6) Samuel J. Lee - "Synthesis of sol-gel phase-reversible hydrogels sensitive to glucose"
He graduated with a Ph.D. degree in December 1994 to work as a research scientist at DuPont Biomedical.
- 7) Timothy B. McPherson - "Prevention of protein adsorption by PEO surface modification"
He graduated with a Ph.D. degree in December 1995. After working as a postdoc in Bioengineering Department of Purdue University, he became Assistant Professor at College of Pharmacy, Saint Louis University.
- 8) Aiman A. Obaidat - "Characterization of glucose dependent gel-sol phase transition of the polymeric glucose-concanavalin a hydrogel"
He graduated with a Ph.D. degree in June 1996 to become Assistant Professor at School of Pharmacy, Jordan University of Science and Technology, Irbid, Jordan.
- 9) Jun Chen - "Superporous hydrogels: Synthesis and applications"
He graduated with a Ph.D. degree in January 1997 to work as a research scientist at Merck.
- 10) Rosalind Jackson - "Preparation of alginate microparticles by emulsification for oral vaccine delivery"
She graduated with a Ph.D. degree in May 1997 to work as a research scientist at McNeil Consumer Products Company.

- 11) Seongbong Jo - "Synthesis of applications of silanated poly(ethylene glycol)s"
He graduated with a Ph.D. degree in May 1998.
- 12) Argaw Kidane - "PEO grafting on biomaterial surfaces using gamma-irradiation"
He graduated with a Ph.D. degree in May 1996 to work at Upjohn Company.
- 13) Tonglei Li - "Fractal analysis of surface roughness and study of etching mechanism of acetaminophen single crystals"
He graduated with a Ph.D. degree in April 1999 and became an Assistant Professor at University of Kentucky.
- 14) Richard Gemeinhart - "Properties of superporous hydrogels for drug delivery"
He graduated with a Ph.D. degree in 2000 and became an Assistant Professor at University of Illinois at Chicago.
- 15) Jung Ju Kim - "Glucose-sensitive phase-reversible hydrogels"
He graduated with a Ph.D. degree in 2001 and became a group leader at Pacific Corporation in Korea.
- 16) Nam-Jin Baek - "Drug delivery from stents"
Graduated with a Ph.D. degree in July 2002 and became a group leader at Samyang Research Center-USA.
- 17) Hong Wen-"Atomic force microscopic examination of crystal dissolution patterns."
Graduated with a Ph.D. degree in September 2002. Wyeth Pharmaceutical Inc.
- 18) Yong Qiu - "Development of elastic superporous hydrogels."
Graduated with a Ph.D. degree in December 2002 and is now with IMPAX Laboratories, Inc.
- 19) Yoon Yeo-"Solvent exchange method- a novel microencapsulation technique."
Graduated with a Ph.D. degree in November 2003 and is now on the faculty at Purdue University.
- 20) Mark E. Byrne (NSF IGERT Fellow, Department of Chemical Engineering) - "Glucose sensitive molecules: Applications to biosensors" (Co-advisor with Professor Nicholas Peppas at Department of Chemical Engineering).
Graduated with a Ph.D. degree in 2003 and is now an Assistant Professor at Auburn University.
- 21) Yourong Fu - "Novel method of making fast dissolving tablets"
Graduated with a Ph.D. degree in 2004 and is now with Akina, Inc.
- 22) David Henthorn (NSF IGERT Fellow, Department of Chemical Engineering) - "Modeling of novel multi-methacrylate polymerization" (Co-advisor with Professor Nicholas Peppas at Department of Chemical Engineering).
Graduated with a Ph.D. degree in 2004. Assistant Professor at University of Missouri-Rolla.
- 23) Kimberly Hayden (NSF IGERT Fellow, Department of Chemical Engineering) - "Effect of particle surface characteristics on particle transport" (Co-advisor with Professor Jennifer Sinclair at Department of Chemical Engineering).
Graduated with a Ph.D. degree in 2003 and is now an Assistant Professor at University of Missouri-Rolla.

- 24) Jay Blachard (NSF IGERT Fellow, Department of Biomedical Engineering) - "Controlled drug delivery using pH-sensitive hydrogels" (Co-advisor with Professor Nicholas Peppas at Department of Chemical Engineering).
August 2000 - December 2002 (Moved to University of Texas at Austin).
- 25) Grace Jun-Park (NSF IGERT Fellow, Department of Pharmaceutics) - "Surface modified PLGA/carbon nanofiber composites enhance articular chondrocyte functions" (Co-advisor with Professor Tom Webster at Department of Biomedical Engineering).
Graduated with a Ph.D. degree in December 2005 and is with Becton, Dickinson & Co. (BD) at Franklin Lakes, NJ.
- 26) Seonghoon Jeong- "Sustained release of fast-melting tablets using various polymer coated ion-exchange resin complexes"
Graduated with a Ph.D. degree in 2005. Wyeth Pharmaceuticals
Professor at Busan National University in Korea.
- 27) Connie Paul (NSF IGERT Fellow, Department of Pharmaceutics)- "The microenvironment-controlled encapsulation (mice) process for drug delivery" Co-advisor with Professor Paul Robinson at School of Veterinary Sciences).
Graduated with a Ph.D. degree in August 2006 and is currently an associate scientist with Elan Pharmaceuticals.
- 28) Eunah Kang-"Drug eluting stent and its characterization by coherent anti-Stokes Raman scattering microscopy"
Graduated with a Ph.D. degree in Biomedical Engineering in 2007
A postdoc at Korea Institute of Science and Technology.
- 29) Mingli Ye- "Factors controlling the microcapsules prepared by the solvent exchange method"
Graduated with a Ph.D. degree in 2008.
A postdoctoral research associate with the Engineering Research Center for Structure Organic Particulate Systems, School of Chemical Engineering, Purdue University.
- 30) Kwang Su Seo - "Novel ultrasonic atomizer approach for making microcapsules"
Graduated with a master's degree in Biomedical Engineering in 2006.
A Ph.D. graduate student at University of Akron.
- 31) Kumar Vedantham - "Development of two-drug eluting stents"
August 2005 - October 2009
Postdoc training at Mechanical Engineering and Engineering Science Department, The University of North Carolina at Charlotte.
- 32) Somali Chaterji - "Endothelial cell culture on smooth muscle cell surface"
August 2005 - December 2009.
- 33) Ji Young Kim - "Hydrotropic solubilization of poorly soluble drugs"
January 2006 -August 2009
LG Life Science.
- 34) Jutarat Kitsongsermthorn - "Multiple drug release from stents"
August 2006 -October 2011.
- 35) Namho Kim - "Drug release for promoting endothelial cell growth"

August 2008 - July 2010.

- 35) Ying Lu- “Drug-eluting stents using nanofabricated drug crystals”
July 2009 - 2013.
- 36) Yuanzu He- “Effect of microparticle shape and size on cell endocytosis”
July 2010 - 2012.
- 37) Crystal Soo Jung Shin: “Nanofabrication of anticancer drug delivery systems”
January 2010 - June 2014.
- 38) Matthew McDermot: "An evaluation of tetramethyl orthosilicate as a vehicle for anti-inflammatory delivery after microelectrode implantation"
July 2011 - present (Co-advisor: Professor Kevin Otto).
- 39) Mark Hamilton- “Blood glucose detection from exhaled breath condensate”
May 2012 - May 2014 (Co-advisor: Professor Ann Rundell).
- 40) Ben Kline - “Interplay between polymer and solvent in microparticle formulation”
July 2012 - May 2014.
- 41) Heui Chang Lee- “Device design factors for enhancing the functionality of chronic intracortical microelectrodes”
July 2012 - December 2016 (Co-advisor: Professor Kevin Otto).

Post-docs and visiting scientists

- 1) Professor Chang-Koo Shim, Ph.D., November, 1988 - October, 1989.
- 2) Yin-Chao Tseng, Ph.D., July, 1989 - June, 1992.
- 3) Annamaria Paparella, Ph.D., October, 1993 - May, 1994.
- 4) Professor Sung-Ju Hwang, Ph.D., June, 1996 - June, 1998.
- 5) Jin-Chul Kim, Ph.D., July, 1997 - June, 1999.
- 6) Professor Ki-Young Lee, Ph.D., June, 1998 - September, 1998.
- 7) Won-Moon Choi, Ph.D. October, 1998 - September, 2000
- 8) Professor Jin-Ho Lee, Ph.D. March, 1999 - February, 2000
- 9) Hasoo Seong, Ph.D. November 1999 - November 2000
- 10) Yong Keun Chang, Ph.D., March 2000 - August 2000
- 11) Ghanashyam Acharya, Ph.D. March 2000 - February 2001
- 12) Jaehwi Lee, Ph.D. April 2000 - February 2004
- 13) Dukjoon Kim, Ph.D. January 2001- July 2002
- 14) Sang Cheon Lee, Ph.D. March 2001- December 2003
- 15) Hossein Omidian, Ph.D., March 2001- April 2002
- 16) Shi Cheng Yang, Ph.D., May 2001- June 2003
- 17) Tooru Ooya, Ph.D., September 2001- September 2002
- 18) Tomohiro, Konno, October, 2001
- 19) Seon Haeng Cho, Ph.D., October 2001- December 2002

- 20) Jong-Duk Kim, Ph.D. October 2001-September 2002
- 21) Byoung Yoon Kim, December 2001 - June 2002
- 22) Seung Rim Yang, July 2002 - December 2002
- 23) Jae Hyun Jeong, July 2003-December 2003
- 24) Susumu Kimura, Ph.D., August 2003-February 2005
- 25) Kang Moo Huh, Ph.D., December 2003 - October 2004
- 26) Jae Hyung Park, Ph.D., March 2004 - August 2005
- 27) Ji-Young Kim. M.S., June 2004 - January 2005
- 28) Sangyoun Lee, June 2004 – June 2006
- 29) Woo-Kyung Lee, Ph.D., July 2004 - February 2005
- 30) Dae Keon Choi, Ph.D., September 2004 - January 2006
- 31) Bong Sik Jeon, March 2005 - August 2005
- 31) Il Keun Kwon, Ph.D., March 2005 - February 2007
- 32) Woo Sun Shim, Ph.D., August 2005 - September 2006
- 33) Seonghoon Jeong, Ph.D., December 2005 - March 2006
- 34) Je Kyo Jeong, Ph.D. March 2006 - September 2006
- 35) Hatem Hegazy, March 2006 - September 2006
- 36) Sungwon Kim, Ph.D., August 2006 – September 2011
- 37) Xiaohong Wei, Ph.D., October 2006 - September 2007
- 38) Jong-Ho Kim, Ph.D. March 2007 - June 2008
- 39) Oju Jeon, Ph.D., April 2007 – March 2008
- 40) Yuuki Takaishi, October 2007 – September 2008
- 41) Ghanashyam Acharya, Ph.D. September 2007 –March 2011
- 42) Kyungmin Shin. August 2008 - July 2009
- 43) Kyeongsoon Park, Ph.D. August 2008 - July 2009
- 44) Nazgul Myzhanova, October - November 2008
- 45) Ayauzhan Tumabayeva, October - November 2008
- 46) Da-Won Oh. February 2009 - August 2009
- 47) Sungwon An. May 2009 - April 2010
- 48) Yeon Hee Yun, July 2009 - November 2009
- 49) Yoshio Kuno, Ph.D., October 2009 - September 2010
- 50) Professor Sung Soo Han, Ph.D. February 2010 - January 2011
- 51) Jung Min Cho, May 2010 - July 2011
- 52) Ki Young Choi, Ph.D.. August 2010 - July 2011
- 53) Byung Kook Lee, Ph.D., January 2011- August 2017
- 54) Yeon Hee Yun, Ph.D., May 2011 – January 2018
- 55) Professor Wenping Wang, Ph.D., November 2011 - November 2012
- 56) Byung-Dong Hahn, Ph.D., February 2012 – January 2013
- 57) Professor Yuhua Ma, M.S., March 2012 – February 2013
- 58) Professor Shengjiu Gu, Ph.D., March 2012 - September 2012

- 59) Professor Senlin Shi, Ph.D., June 2012 - May 2013
- 60) Professor Zhongqiong Qu, Ph.D., August 2012 -July 2013
- 61) Professor Nian-Ping Feng, Ph.D., August 2012 - July 2013
- 62) Professor Fei Qiu, Ph.D., September 2012 - August 2013
- 63) Jinhyun Hannah Lee, Ph.D., March 2013 - February 2014.
- 64) Professor Juqun Xi, Ph.D., August 2013 – August 2014
- 65) Professor Xueying Yan, Ph.D., February 2014 – January 2015
- 66) Yongjuan Shi, September 2014 - September 2015
- 67) Professor Xu Lu, Ph.D., October 2014 - October 2015
- 68) Andrew Otte, Ph.D., October 2014 – August 2019
- 69) Youngnam Lee, M.S., November 2014 - October 2016
- 70) Bong Kwan Soh, M.S., November 2014 – October 2019
- 71) Chang Geun Song, M.S., November 2014 - December 2015
- 72) Yahira Baez, Ph.D., November 2014 - October 2016
- 73) Professor Ming-Tao Zhang, PhD, December 2014 - August 2017
- 74) Seungman Park, Ph.D., December 2014 - November 2015
- 75) Ayauzhan Tumabayeva, M.S., January 2015 - December 2015
- 76) Professor Zhuangzhi Zhi, Ph.D., January 2015 - January 2016
- 77) Ellina Mun, Ph.D., November 2015 - September 2017
- 78) Daekoo Woo, M.S., October 2016 - August 2017
- 79) Haoying Yu, M.S., February 2017 - June 2017
- 80) Gwang Heum Yoon, M.S., October 2016 -
- 81) Dijia Yu, M.S., November 2017 - November 2018
- 82) Shweta Sharma, Ph.D., February 2018 -
- 83) Farrokh Sharifi, Ph.D., August 2018 -


Manuscript Reviews for Journals

ACS Advanced Chemistry Series
Acta Anatomica
Analytical Chemistry
American Journal of Pathology
American Journal of Transplantation
Bioconjugate Chemistry
Biomacromolecules
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Biotechnology and Bioengineering
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Eur. J. Pharmaceutics & Biopharmaceutics
European Polymer Journal
Fundamental and Applied Toxicology
IEEE Transaction on Biomedical Engineering

International Journal of Cancer
International Journal of Pharmaceutics
Journal of Adhesion
Journal of Applied Polymer Science
Journal of American Chemical Society
Journal of Bioactive and Compatible Polymers
Journal of Biomaterials Science-Polymer Edition
Journal of Biomedical Materials Research
Journal of Colloid and Interface Science
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Journal of Membrane Science
Journal of Pharmaceutical Science
Journal of Physical Chemistry. Letters Section
Journal of Polymer Science. Part A: Polymer Chemistry
Langmuir
Macromolecules
Molecular Therapy/Genomics
NanoLetters
Nature Biotechnology
Nature Nanotechnology
Polymer
Pharmaceutical Development and Technology
Pharmaceutical Research
PharmSciTech
Proceedings of the National Academy of Sciences, USA
Reactive and Functional Polymers
Scanning Microscopy
Separation Science and Technology
Trends in Polymer Science

EXHIBIT 11

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

<p>PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC and ENDO PAR INNOVATION COMPANY, LLC,</p> <p>Plaintiffs,</p> <p>v.</p> <p>EAGLE PHARMACEUTICALS INC.,</p> <p>Defendant.</p>	<p>C.A. No. 18-cv-823-CFC</p> <p></p>
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PLAINTIFFS' DEPOSITION DESIGNATIONS

Pursuant to Local Rule 16.3(c)(7), Plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC (collectively "Plaintiffs") submit herein their list of deposition designations, Defendant's objections to Plaintiffs' designations, Defendant's counter-designations, and Plaintiffs' objections to such counter-designations. Plaintiffs reserve the right to counter-designate testimony in response to Defendant's designations.

Exhibit 11

Aungst, Ron 10/13/2019					
Par's Initial Designations		Eagle's Objections	Eagle's Counter Designations		Par's Objections
From	To		From	To	
6:5	6:8				
6:10	6:15				
9:3	10:3				
10:7	10:11				
10:17	10:19	Form			
10:23	11:4				
11:23	12:4				
16:6	17:2	Inc., R, 403			
18:14	18:24				
19:3	20:2				
20:7	21:13	R, 403	21:14	21:16	
			73:3	73:13	OS, 401, 402, 403
			75:25	76:23	401, 402, 403, 602, 701, 702
21:17	21:25	R, 403			
22:16	23:3	R, 403	23:4	23:5	401, 402, 403, 602
			23:8	23:12	401, 402, 403, 602
25:6	27:10	R, 403			
27:15	27:24	R, 403	27:25	28:2	
28:3	28:14				
34:13	35:10	R, 403			
36:3	36:17	R, 403			
40:10	40:16	R, 403			
45:13	46:25	R, 403			
47:8	48:8	Form, R, 403			

Exhibit 1

Aungst, Ron 10/13/2019					
Par's Initial Designations		Eagle's Objections	Eagle's Counter Designations		Par's Objections
From	To		From	To	
48:10	48:11	Form, R, 403			
48:20	48:22	R, 403			
49:8	51:21	Form, H, R, 403			
51:24	51:25	Form			
52:3	55:6	Form, H, R, 403, S			
55:9	55:9	Form, R, 403, S			
55:11	55:22	R, 403, S			
56:24	57:3	Form	63:23	64:9	OS, 401, 402, 403
57:5	57:16	Form	63:23	64:9	OS, 401, 402, 403
57:18	57:25		63:23	64:9	OS, 401, 402, 403
58:14	59:7	R, 403			
65:8	65:23	R, 403	65:4	65:7	
66:3	66:21	R, 403, S			
67:5	68:13	R, 403, S			
77:4	78:15	R, 403			
80:3	80:21	H, R, 403	81:5	81:16	
82:4	82:16				
82:25	83:6				
85:7	87:11	Form, H, R, 403, S, Lay			
93:7	93:10	Form, R, 403, S, Lay	90:11	90:14	NR, 401, 402, 403, 602, 701, 702
			90:17	90:24	NR, 401, 402, 403, 602, 701, 702

Exhibit 1

Aungst, Ron 10/13/2019					
Par's Initial Designations		Eagle's Objections	Eagle's Counter Designations		Par's Objections
From	To		From	To	
93:15	94:5	Form, R, 403, S, Lay	90:11	90:14	NR, 401, 402, 403, 602, 701, 702
			90:17	90:24	NR, 401, 402, 403, 602, 701, 702
100:13	100:15				
100:20	101:7	F			
102:6	102:16				
103:2	103:25	F, S	161:10	161:12	OS, 401, 402, 403, 602
			161:14	161:24	OS, 401, 402, 403, 602
104:23	105:11	F, R, 403			
106:3	106:6	F, R, 403, S	105:23	106:2	OS, NR, 106, 401, 402, 403, 602, 701, 702
			106:7	106:22	V, 106, 401, 402, 403, 602, 701, 702
			107:10	107:17	401, 402, 403, 602
107:18	108:8	Form, R, 403, F, S	107:10	107:17	401, 402, 403, 602

Exhibit 11

Aungst, Ron 10/13/2019					
Par's Initial Designations		Eagle's Objections	Eagle's Counter Designations		Par's Objections
From	To		From	To	
110:8	110:13	Form, R, 403, F, S	105:12	105:15	OS, NR, 106, 401, 402, 403, 602, 701, 702
			105:17	105:21	OS, NR, 106, 401, 402, 403, 602, 701, 702
			105:23	106:2	OS, NR, 106, 401, 402, 403, 602, 701, 702
			106:7	106:22	V, 106, 401, 402, 403, 602, 701, 702
			109:16	109:21	NR, 106, 401, 402, 403, 602
			109:24	110:4	OS, NR, 106, 401, 402, 403, 602
			111:2	111:9	OS, NR, 106, 401, 402, 403, 602
			111:14	111:23	OS, NR, 106, 401, 402, 403, 602
			112:7	112:8	OS, NR, 106, 401, 402, 403, 602
			138:15	139:3	OS, NR, 106, 401, 402, 403, 602, 701, 702
			139:6	139:7	OS, NR, 106, 401, 402, 403, 602, 701, 702
			139:9	139:13	OS, NR, 106, 401, 402, 403, 602, 701, 702
			139:15	140:13	OS, NR, 106, 401, 402, 403, 602, 701, 702

Exhibit 1

Aungst, Ron 10/13/2019					
Par's Initial Designations		Eagle's Objections	Eagle's Counter Designations		Par's Objections
From	To		From	To	
110:16	110:17	Form, R, 403, F, S	105:12	105:15	OS, NR, 106, 401, 402, 403, 602, 701, 702
			105:17	105:21	OS, NR, 106, 401, 402, 403, 602, 701, 702
			105:23	106:2	OS, NR, 106, 401, 402, 403, 602, 701, 702
			106:7	106:22	V, 106, 401, 402, 403, 602, 701, 702
			109:24	110:4	OS, NR, 106, 401, 402, 403, 602
			111:2	111:9	NR, 106, 401, 402, 403, 602
			111:14	111:23	OS, NR, 106, 401, 402, 403, 602
			112:7	112:8	OS, NR, 106, 401, 402, 403, 602
			138:15	139:3	OS, NR, 106, 401, 402, 403, 602
			139:6	139:7	OS, NR, 106, 401, 402, 403, 602, 701, 702
			139:9	139:13	OS, NR, 106, 401, 402, 403, 602, 701, 702
			139:15	140:13	OS, NR, 106, 401, 402, 403, 602, 701, 702

Exhibit 1

Aungst, Ron 10/13/2019					
Par's Initial Designations		Eagle's Objections	Eagle's Counter Designations		Par's Objections
From	To		From	To	
113:13	113:21	Form, R, 403, F, S	105:12	105:15	OS, NR, 106, 401, 402, 403, 602, 701, 702
			105:17	105:21	OS, NR, 106, 401, 402, 403, 602, 701, 702
			105:23	106:2	OS, NR, 106, 401, 402, 403, 602, 701, 702
			106:7	106:22	V, 106, 401, 402, 403, 602, 701, 702
			109:24	110:4	OS, NR, 106, 401, 402, 403, 602
			111:2	111:9	NR, 106, 401, 402, 403, 602
			111:14	111:23	OS, NR, 106, 401, 402, 403, 602
			112:7	112:8	OS, NR, 106, 401, 402, 403, 602
			138:15	139:3	OS, NR, 106, 401, 402, 403, 602
			139:6	139:7	OS, NR, 106, 401, 402, 403, 602, 701, 702
			139:9	139:13	OS, NR, 106, 401, 402, 403, 602, 701, 702
			139:15	140:13	OS, NR, 106, 401, 402, 403, 602, 701, 702

Exhibit 1

Aungst, Ron 10/13/2019					
Par's Initial Designations		Eagle's Objections	Eagle's Counter Designations		Par's Objections
From	To		From	To	
113:25	114:4	Form, R, 403, F, S	105:12	105:15	OS, NR, 106, 401, 402, 403, 602, 701, 702
			105:17	105:21	OS, NR, 106, 401, 402, 403, 602, 701, 702
			105:23	106:2	OS, NR, 106, 401, 402, 403, 602, 701, 702
			106:7	106:22	V, 106, 401, 402, 403, 602, 701, 702
			109:24	110:4	OS, NR, 106, 401, 402, 403, 602
			111:2	111:9	NR, 106, 401, 402, 403, 602
			111:14	111:23	OS, NR, 106, 401, 402, 403, 602
			112:7	112:8	OS, NR, 106, 401, 402, 403, 602
			138:15	139:3	OS, NR, 106, 401, 402, 403, 602
			139:6	139:7	OS, NR, 106, 401, 402, 403, 602, 701, 702
			139:9	139:13	OS, NR, 106, 401, 402, 403, 602, 701, 702
			139:15	140:13	OS, NR, 106, 401, 402, 403, 602, 701, 702
116:21	117:9	H, R, 403	117:10	119:4	
119:5	120:15	Form, H, R, 403	135:18	136:9	

Exhibit 1

Aungst, Ron 10/13/2019					
Par's Initial Designations		Eagle's Objections	Eagle's Counter Designations		Par's Objections
From	To		From	To	
120:17	120:18	Form, H, R, 403	135:18	136:9	
120:20	122:6	R, 403, F, S	122:7	122:9	
			122:11	122:20	
136:10	137:20	F			
153:17	153:24				
154:3	157:7	H, R, 403, S, Lay			
158:4	159:5	R, 403			
161:6	161:9	R, 403			
162:14	164:4	R, 403			
164:17	166:18	Form, R, 403			
166:20	166:23	Form, R, 403			
166:25	167:8	R, 403			
168:5	169:20		169:21	170:6	V, 401,402, 403, 602, 701, 702
			170:25	171:4	
174:14	174:24				
176:16	177:25	H			
178:8	180:3	R, 403			
180:19	181:6				
181:11	182:18	H, R, 403			
183:20	186:4				
186:9	186:19	F			
187:2	187:16	H, F, Lay			

Exhibit 1

Aungst, Ron 10/13/2019					
Par's Initial Designations		Eagle's Objections	Eagle's Counter Designations		Par's Objections
From	To		From	To	
188:13	188:25				
189:25	193:8	R, 403			
193:13	194:25	H, R, 403			
195:9	195:14	R, 403			
197:8	198:6	R, 403			
198:11	198:22				
200:16	202:8	H, R, 403			
202:14	202:25	H, R, 403			
203:25	204:13	R, 403			
207:13	208:13	R, 403			
212:9	212:18				
213:4	213:9				
213:21	215:25	H, R, 403	219:2	219:13	NR, OS, 401, 402, 403
			221:5	221:9	NR, OS, 401, 402, 403
			221:11	221:12	NR, OS, 401, 402, 403
			221:14	221:17	NR, OS, 401, 402, 403
			222:12	223:4	NR, OS, 401, 402, 403
216:5	218:4	H, R, 403	219:2	219:13	NR, OS, 401, 402, 403
			221:5	221:9	NR, OS, 401, 402, 403
			221:11	221:12	NR, OS, 401, 402, 403
			221:14	221:17	NR, OS, 401, 402, 403
			222:12	223:4	NR, OS, 401, 402, 403
225:6	227:25	H, R, 403, F, AF, Lay			
231:16	232:23				

Exhibit 1

Aungst, Ron 10/13/2019					
Par's Initial Designations		Eagle's Objections	Eagle's Counter Designations		Par's Objections
From	To		From	To	
233:16	234:23	R, 403			
241:15	242:9	R, 403			
242:14	242:19				
243:3	243:9				
243:15	243:25				
244:11	246:12	H, R, 403			
247:20	248:2	R, 403			
254:24	262:2	H, R, 403			
262:24	264:7	R, 403			
264:10	267:7	H, R, 403, S, Lay			
267:21	269:9				
270:4	271:8	R, 403, S			
271:23	272:21	H, R, 403			
273:2	274:23	Form, H, R, 403, S	275:19	276:14	
274:25	275:4	Form, R, 403, F, S	275:19	276:14	
277:3	280:19	Form, H, R, 403, F			
280:21	280:24	Form, R, 403, F			
281:3	281:6				
284:6	286:7	H, R, 403, F			
287:11	288:22	H, R, 403, F			
289:4	291:4	R, 403			
293:19	293:22				
293:25	294:21	H, R, 403			

Exhibit 11

Hepner, Adrian 10/25/2019					
Par's Initial Designations		Eagle's Objections	Eagle's Counter Designations		Par's Objections
From	To		From	To	
5:16	5:19				
5:22	6:2				
14:15	15:6				
15:12	15:19				
24:2	26:2	R, 403			
32:16	33:17	H, R, 403	33:18	34:4	401, 402, 403
			34:6	34:9	401, 402, 403, 801, 802
39:4	42:19	R, 403			
45:9	47:17	R, 403			
47:22	48:17	H			
49:23	49:24	Form, R, 403			
50:3	50:5	R, 403			
50:7	51:3				
52:4	53:3	R, 403, S	53:4	53:11	401, 402, 403, 602, 701, 702, 801, 802
54:9	54:24	R, 403, S			
60:3	60:9	R, 403, S, Lay	59:25	60:2	OS, 401, 402, 403, 602, 702, 702
			60:10	60:18	OS, 401, 402, 403, 602, 702, 702, 801, 802
			62:5	62:13	OS, 401, 402, 403, 602, 801, 802
66:12	66:23	H			
72:15	72:21	R, 403, S			

Exhibit 1

Hepner, Adrian 10/25/2019					
Par's Initial Designations		Eagle's Objections	Eagle's Counter Designations		Par's Objections
From	To		From	To	
77:5	77:9	Form, H, R, 403, Lay			
77:11	77:11	Form, H, R, 403, Lay			
80:22	81:19	H, R, 403, Lay			
84:12	85:7	H, R, 403, S, Lay	85:8	85:15	401, 402, 403, 602, 701, 702, 801, 802
85:16	85:21	R, 403, S, Lay	85:8	85:15	401, 402, 403, 602, 701, 702, 801, 802
88:6	88:12	H, R, 403, Lay			
88:22	88:25	R, 403	88:13	88:21	
91:2	91:25	H, R, 403			
98:6	99:18	H, R, 403, S, Lay			
104:11	105:25	H, R, 403, S, Lay			
108:23	109:5				
109:17	109:21				
111:9	111:14				
111:22	112:8	H, R, 403, S, Lay			
114:20	115:10				
115:22	116:2	H			
116:8	118:9	H, R, 403			
137:17	138:3				
139:2	141:5	H, R, 403			

Exhibit 1

Hepner, Adrian 10/25/2019					
Par's Initial Designations		Eagle's Objections	Eagle's Counter Designations		Par's Objections
From	To		From	To	
147:22	147:24	Form, R, 403	142:10	142:17	OS, NR, 106, 401, 402, 403, 801, 802
			145:20	146:8	OS, NR, 106, 401, 402, 403, 801, 802
			146:11	146:16	OS, NR, 106, 401, 402, 403, 801, 802
			148:13	148:25	OS, NR, 106, 401, 402, 403, 801, 802
			149:4	149:8	OS, NR, 106, 401, 402, 403, 801, 802
			154:18	154:22	OS, NR, 106, 401, 402, 403, 602, 701, 702, 801, 802
			154:25	155:5	OS, NR, 106, 401, 402, 403, 602, 701, 702, 801, 802

Exhibit 11

Hepner, Adrian 10/25/2019					
Par's Initial Designations		Eagle's Objections	Eagle's Counter Designations		Par's Objections
From	To		From	To	
148:2	148:12	Form, R, 403	142:10	142:17	OS, NR, 106, 401, 402, 403, 801, 802
			145:20	146:8	OS, NR, 106, 401, 402, 403, 801, 802
			146:11	146:16	OS, NR, 106, 401, 402, 403, 801, 802
			148:13	148:25	OS, NR, 106, 401, 402, 403, 801, 802
			149:4	149:8	OS, NR, 106, 401, 402, 403, 801, 802
			154:18	154:22	OS, NR, 106, 401, 402, 403, 602, 701, 702, 801, 802
			154:25	155:5	OS, NR, 106, 401, 402, 403, 602, 701, 702, 801, 802

Exhibit 1

Hepner, Adrian 10/25/2019					
Par's Initial Designations		Eagle's Objections	Eagle's Counter Designations		Par's Objections
From	To		From	To	
155:21	156:2	R, 403, AF, F, S			
156:6	156:11				
156:13	158:11	Form, H, R, 403	159:8	159:20	OS, NR, 401, 402, 403, 602, 701, 702, 801, 802
			159:23	160:5	OS, NR, 401, 402, 403, 602, 701, 702, 801, 802
158:14	158:17	Form, H, R, 403	159:8	159:20	OS, NR, 401, 402, 403, 602, 701, 702, 801, 802
			159:23	160:5	OS, NR, 401, 402, 403, 602, 701, 702, 801, 802
158:19	158:21	H, R, 403	159:8	159:20	OS, NR, 401, 402, 403, 602, 701, 702, 801, 802
			159:23	160:5	
173:7	173:9	R, 403, AF, F, S			
173:14	173:19				
174:3	174:12				
177:12	179:10	Form, H, Lay	179:20	180:2	
179:12	179:12	Form, Lay	179:20	180:2	
179:14	179:19	R, 403	179:20	180:2	
180:3	180:7	Form, R, 403, Lay	179:20	180:2	
180:9	180:11	Form, R, 403, Lay	179:20	180:2	
180:13	180:19	Form, R, 403, Lay	179:20	180:2	
180:21	180:23	Form, R, 403, Lay	179:20	180:2	
180:25	183:2	H, R, 403, Lay			

Exhibit 1

Hepner, Adrian 10/25/2019					
Par's Initial Designations		Eagle's Objections	Eagle's Counter Designations		Par's Objections
From	To		From	To	
183:8	183:20	H, R, 403, Lay			
184:4	184:25	H, R, 403, Lay			
187:13	189:22	H, R, 403, S, Lay			
191:15	191:17	R, 403			
192:2	192:7	R, 403, S			
194:21	195:3	R, 403			
195:14	196:10				
198:8	198:21	R, 403	199:2	199:4	V, 401, 402, 403, 602, 801, 802
			199:6	199:16	V, 401, 402, 403, 602, 801, 802
208:19	210:4	R, 403			

Exhibit 17

Romito, James 10/09/2019					
Par's Initial Designations		Eagle's Objections	Eagle's Counter Designations		Par's Objections
From	To		From	To	
5:23	6:2				
6:4	6:8				
8:13	9:17				
9:24	11:16	Form, C			
12:20	13:4				
19:22	22:7	R, 403			
31:9	31:23	H, AF, F	29:11	29:16	
			29:18	29:19	
36:25	37:4	F			
37:8	38:12	F	34:19	34:23	
			35:7	35:13	
38:21	40:3	F			
46:7	46:12	F			
46:19	47:17	F			
47:25	48:10	F			
48:12	48:12	F			
48:14	48:23	F			
49:7	49:17	F			
49:19	50:5	F			
50:15	50:19				
50:22	51:16				
52:13	52:25				
53:9	53:18	R, 403	53:19	53:23	
			58:5	60:5	OS, 401, 402, 403, 801, 802

Exhibit 1

Romito, James 10/09/2019					
Par's Initial Designations		Eagle's Objections	Eagle's Counter Designations		Par's Objections
From	To		From	To	
55:3	55:6	R, 403			
57:13	57:24	R, 403, AF, F	40:25	41:11	
			41:13	41:22	
			42:4	42:14	
			43:15	43:24	
			44:17	45:14	
			58:5	60:5	OS, 401, 402, 403, 801, 802
60:22	61:25	R, 403	58:5	60:5	OS, 401, 402, 403, 801, 802
			62:2	62:14	OS, 401, 402, 403, 801, 802
62:15	64:21	H, R, 403, Lay	62:2	62:14	OS, 401, 402, 403, 801, 802
			64:22	66:22	OS, 401, 402, 403, 602, 701, 702, 801, 802
			66:24	66:25	OS, 401, 402, 403, 602, 701, 702, 801, 802
			67:3	70:21	OS, 401, 402, 403, 602, 701, 702, 801, 802
73:25	74:23	H, R, 403, F			
76:25	77:21	R, 403, F			
80:4	82:15	H, R, 403			
83:5	84:6	Form, R, 403			
84:10	84:23	Form, R, 403			
84:25	85:2	Form, R, 403			

Exhibit 1

Romito, James 10/09/2019					
Par's Initial Designations		Eagle's Objections	Eagle's Counter Designations		Par's Objections
From	To		From	To	
85:8	85:10		100:21	101:7	OS, 106, 401, 402, 403
			102:5	102:18	OS, 106, 401, 402, 403
			111:21	112:10	OS, 106, 401, 402, 403, 602, 801, 802
85:12	85:12		100:21	101:7	OS, 106, 401, 402, 403
			102:5	102:18	OS, 106, 401, 402, 403
			111:21	112:10	OS, 106, 401, 402, 403, 602, 801, 802
85:14	86:3	Form, H	100:21	101:7	OS, 106, 401, 402, 403
			102:5	102:18	OS, 106, 401, 402, 403
			111:21	112:10	OS, 106, 401, 402, 403, 602, 801, 802
86:7	86:8	Form, H	100:21	101:7	OS, 106, 401, 402, 403
			102:5	102:18	OS, 106, 401, 402, 403
			111:21	112:10	OS, 106, 401, 402, 403, 602, 801, 802
89:3	90:9	Form, H, R, 403			
90:19	90:22				
92:10	94:17	H, R, 403, S			

Exhibit 1

Romito, James 10/09/2019					
Par's Initial Designations		Eagle's Objections	Eagle's Counter Designations		Par's Objections
From	To		From	To	
94:25	96:14	Form, R, 403, F, S	207:2	207:7	401, 402, 403, 602, 701, 702, 801, 802
			207:9	207:9	401, 402, 403, 602, 701, 702, 801, 802
			207:11	207:20	401, 402, 403, 602, 701, 702, 801, 802
			207:23	207:23	401, 402, 403, 602, 701, 702, 801, 802
			207:25	208:18	401, 402, 403, 602, 701, 702, 801, 802
			211:4	211:11	401, 402, 403, 602, 701, 702, 801, 802
			211:16	211:24	401, 402, 403, 602, 701, 702, 801, 802
			212:3	212:4	401, 402, 403, 602, 701, 702, 801, 802
			212:17	212:21	401, 402, 403, 602, 701, 702, 801, 802
			212:24	213:3	401, 402, 403, 602, 701, 702, 801, 802
96:17	97:3	Form, R, 403, F, S			
97:6	97:7	Form, R, 403, F, S			
97:9	97:25	Form, R, 403, F, S			
98:4	98:4	Form, R, 403, F, S			

Exhibit 11

Romito, James 10/09/2019					
Par's Initial Designations		Eagle's Objections	Eagle's Counter Designations		Par's Objections
From	To		From	To	
98:17	98:20	R, 403	98:21	98:24	401, 402, 403, 602, 801, 802
			99:3	99:3	401, 402, 403, 602, 801, 802
			99:5	99:7	401, 402, 403, 602, 801, 802
			99:10	99:13	401, 402, 403, 602, 801, 802
102:19	102:21	R, 403	102:5	102:18	OS, 106, 401, 402, 403
103:2	105:8	R, 403	102:5	102:18	OS, 106, 401, 402, 403
105:20	106:5	R, 403	111:21	112:10	OS, 106, 401, 402, 403, 602, 801, 802
106:18	106:23	Form, R, 403	111:21	112:10	OS, 106, 401, 402, 403, 602, 801, 802
113:21	114:17	H, R, 403, S			
115:11	115:16	Form, R, 403			
115:18	115:21	Form, R, 403			
115:23	116:21	H, R, 403			
117:3	117:13	R, 403			
124:8	125:9				
125:14	126:19	H, R, 403			
126:25	127:14	H, R, 403	128:15	128:23	401, 402, 403, 801, 802
127:23	128:11	R, 403			
132:22	134:10	Form, R, 403, F, S			
135:2	135:19	Form, F, NQP	134:18	134:24	
			138:14	138:25	401, 402, 403, 602, 801, 802
139:11	139:16	Form, F, S, Lay	144:9	144:13	801, 802
			144:17	144:21	801, 802

Exhibit 1

Romito, James 10/09/2019					
Par's Initial Designations		Eagle's Objections	Eagle's Counter Designations		Par's Objections
From	To		From	To	
139:18	139:19	Form, F, S, Lay	144:9	144:13	801, 802
			144:17	144:21	801, 802
141:10	141:14	Form, F, S, Lay	142:16	142:21	401, 402, 403, 602, 801, 802
			142:25	143:4	401, 402, 403, 602, 801, 802
			144:9	144:13	801, 802
			144:17	144:21	801, 802
147:4	147:18	H			
148:4	148:7	Form, R, 403, S, Lay			
150:10	150:20				
151:9	152:19	R, 403			
152:24	153:16				
153:23	156:24	H, R, 403, S			
157:20	158:6	R, 403			
158:11	158:22				
159:5	160:7	Form, H, R, 403, Lay			
160:10	160:11	Form, H, R, 403			
160:13	160:16	R, 403			
161:7	162:15	H, R, 403, AF, Lay			
164:24	166:18	H, R, 403			
167:11	167:18	R, 403			
168:24	169:24	H, R, 403			
170:5	171:16				
172:4	172:11	R, 403			
173:9	174:4				

Exhibit 1

Romito, James 10/09/2019					
Par's Initial Designations		Eagle's Objections	Eagle's Counter Designations		Par's Objections
From	To		From	To	
174:5	174:7				
174:11	174:12				
174:20	175:3				
177:22	178:5				
178:22	179:17	Form, H, NA			
180:3	181:12	H			
181:17	183:12	H, R, 403, Lay			
183:22	183:25				
185:3	186:4	R, 403, F, Lay			
186:18	187:14	R, 403, F			
190:6	190:19	R, 403, Lay			
191:2	191:11				
191:20	193:2				
193:4	193:24				
196:12	196:17	H, R, 403, Lay			
196:19	197:10	H, R, 403, Lay			
197:23	199:20	H, R, 403, Lay			
202:6	204:5	Form, H, R, 403, AF, F, S, Lay			
204:7	204:9	Form, H, R, 403, AF, F, S, Lay			
204:11	204:20	Form, R, 403, F, S			
205:2	205:15	Form, R, 403, F, S			

Exhibit 11

Romito, James 10/09/2019					
Par's Initial Designations		Eagle's Objections	Eagle's Counter Designations		Par's Objections
From	To		From	To	
209:17	209:21	R, 403	209:4	209:16	401, 402, 403, 602, 701, 702, 801, 802
			211:4	211:11	401, 402, 403, 602, 701, 702, 801, 802
			211:16	211:24	401, 402, 403, 602, 701, 702, 801, 802
			212:3	212:4	401, 402, 403, 602, 701, 702, 801, 802
219:7	219:22	R, 403	209:4	209:16	401, 402, 403, 602, 701, 702, 801, 802
			217:24	218:25	Leading, 401, 402, 403, 602, 701, 702, 801, 802

Exhibit 1

Woltering, Stephen 08/30/2019					
Par's Initial Designations		Eagle's Objections	Eagle's Counter Designations		Par's Objections
From	To		From	To	
17:6	17:12				
19:17	20:11				
20:17	20:18				
20:20	20:23				
20:25	21:14				
21:17	21:19				
22:17	26:25	Form, R, 403			
27:2	27:3	Form			
28:8	28:19				
29:1	29:10				
29:20	29:25	H			
30:8	30:10				
30:18	31:2				
31:6	31:16				
32:2	32:4	R, 403			
33:1	33:7				
33:13	34:10	R, 403, F, S			
34:18	34:19				
34:22	34:22				
34:24	35:19				
36:17	37:16	R, 403, F, S			
39:21	40:19	R, 403			
40:25	41:15				
45:16	46:22	H, R, 403			

Exhibit 1

Woltering, Stephen 08/30/2019					
Par's Initial Designations		Eagle's Objections	Eagle's Counter Designations		Par's Objections
From	To		From	To	
47:15	47:24	F			
48:8	48:18	R, 403, F			
48:23	49:7	R, 403			
50:9	50:13	R, 403, F, S			
50:17	51:20	H			
52:2	52:21	H, R, 403			
54:15	54:21				
56:16	58:15	H, Lay	59:20	59:24	401, 402, 403, 701, 702
			60:17	61:2	401, 402, 403, 701, 702
59:5	59:19	H			
61:19	61:25				
63:5	63:9				
63:19	63:24				
64:8	64:20	H, R, 403			
65:15	67:1	H			
68:3	68:11	H			
68:24	69:9	Form, H, R, 403, F, S	69:10	69:22	401, 402, 403, 602
70:10	72:6	Form, H, R, 403, F, S			
82:9	83:14				
84:1	86:21	H, R, 403, AF, S	86:22	86:24	
86:25	87:8	Lay			
87:10	87:22	H, R, 403			
89:11	90:1	H, R, 403, Lay			
92:3	93:4				

Exhibit 1

Woltering, Stephen 08/30/2019					
Par's Initial Designations		Eagle's Objections	Eagle's Counter Designations		Par's Objections
From	To		From	To	
98:19	99:20	R, 403, S			
102:19	103:9				
103:19	104:8	R, 403, S			
104:16	104:22	H, R, 403			
108:6	108:16	4, 403			
113:24	114:7	R, 403			
115:15	115:23	H, R, 403, F			
117:8	117:14				
117:23	119:12	H			
130:13	130:21	F			
130:24	131:11	F			
131:18	131:20				
132:6	132:9				
133:9	133:23				
134:1	134:22	H			
135:17	136:8	H			
136:13	136:23				
150:18	150:19				
150:23	151:11				
153:8	154:15	H			
159:3	159:8	Lay	159:9	159:12	401, 402, 403, 602, 701, 702
170:13	170:18				
171:19	172:6	R, 403			
179:15	180:4	R, 403			

Exhibit 1

Woltering, Stephen
08/30/2019

Par's Initial Designations		Eagle's Objections	Eagle's Counter Designations		Par's Objections
From	To		From	To	
181:14	181:22	R, 403			
207:16	209:8	R, 403			
209:19	210:3	Form, R, 403			
210:6	210:6	Form, R, 403			
210:13	210:18	R, 403			
211:2	212:11	H, R, 403, S			
212:24	213:6	H, R, 403			
213:9	215:18	H, R, 403			
218:15	219:17	Form, H, R, 403, F, S, Lay	220:11	220:15	401, 402, 403, 602, 701, 702
219:19	219:21	Form, H, R, 403, F, S, Lay	220:11	220:15	401, 402, 403, 602, 701, 702
219:23	219:25	Form, H, R, 403, F, S, Lay	220:11	220:15	401, 402, 403, 602, 701, 702
220:2	220:3	Form, H, R, 403, F, S, Lay	220:11	220:15	401, 402, 403, 602, 701, 702
220:5	220:10	Form, H, R, 403, F, S, Lay	220:11	220:15	401, 402, 403, 602, 701, 702
224:2	224:25	F			
228:20	228:23	Form, H, R, 403, F	231:23	232:1	401, 402, 403, 602, 801, 802
			235:2	235:14	401, 402, 403, 602, 801, 802
228:25	229:3	Form, H, R, 403, F	231:23	232:1	401, 402, 403, 602, 801, 802
			235:2	235:14	
229:5	229:10	Lay			
236:10	236:25	Form, H, R, 403, F, S	235:2	235:14	401, 402, 403, 602, 801, 802
237:2	237:15	Form, H, R, 403, F, S	235:2	235:14	401, 402, 403, 602, 801, 802
247:1	247:10	R, 403	250:19	251:9	401, 402, 403, 602, 701, 702
			252:2	252:10	401, 402, 403, 602, 701, 702
			252:16	252:20	401, 402, 403, 602, 701, 702

Exhibit 1

Woltering, Stephen 08/30/2019					
Par's Initial Designations		Eagle's Objections	Eagle's Counter Designations		Par's Objections
From	To		From	To	
247:17	248:13	Form, R, 403	250:19	251:9	401, 402, 403, 602, 701, 702
			252:2	252:10	401, 402, 403, 602, 701, 702
			252:16	252:20	401, 402, 403, 602, 701, 702
248:15	248:20	Form, 4, 403	250:19	251:9	401, 402, 403, 602, 701, 702
			252:2	252:10	401, 402, 403, 602, 701, 702
			252:16	252:20	401, 402, 403, 602, 701, 702
248:22	248:23	H, R, 403	250:19	251:9	401, 402, 403, 602, 701, 702
			252:2	252:10	401, 402, 403, 602, 701, 702
			252:16	252:20	401, 402, 403, 602, 701, 702
249:18	250:5	Form, H, R, 403			
250:7	250:11	Form, H, R, 403			
250:13	250:16	H, R, 403	250:17	250:18	
253:5	253:15				
255:24	256:9				
257:3	257:18				
259:9	260:3	R, 403, F			
260:14	260:17	R, 403			
272:14	273:6				

Eagle's Objection Code	
CODE	OBJECTION
A	Fed. R. Evid. 901 - Requires proof of authenticity as a condition precedent to its admissibility
DEM	Demonstrative Only
DUP	Duplication of Another Exhibit
E	Mischaracterization in Description
F	Fed. R. Evid. 602 - No Foundation
H	Fed. R. Evid. 801 & 802 - Hearsay
I	Illegible (partly or wholly)
IC	Improper compilation
IN	Fed. R. Evid. 106 - Incomplete
NT	No Certified Translation
R	Fed. R. Evid. 402 - Not Relevant
RD	Redaction Required
26	Fed. R. Civ. P. 26 - Not timely disclosed
403	Fed. R. Evid. 403 - Any relevance substantially outweighed by confusion, prejudice or waster of time
1006	Fed. R. Evid. 1006 - Voluminous document requires summary

Par's Objection Key	
Code	Objection
106	partial document/lacks context (FRE 106)
401/402	lacks relevance (FRE 401/402)
403	unduly prejudicial/confusing/waste of time (FRE 403)
501/502	Privilege/Work Product (FRE 501/502)
602/LOF	lacks foundation/speculative (FRE 602)
701/702	improper opinion (FRE 701/702)
801-802	hearsay (FRE 802)
901/902	lacks authenticity (FRE 901/902)
1002	original document required (FRE 1002)
1003	incomplete/illegible (FRE 1003)
1006	improper summary (FRE 1006)
ID	insufficient/incorrect description
L	late/not produced
AA	attorney argument improperly offered as evidence; contains counsel colloquy or objections
C	compound
Legal	calls for a legal conclusion
Leading	leading question of a non-hostile witness
MC	Mischaracterizes/misstates witness's testimony
NR	nonresponsive
PMIL	Subject of pending motion in limine
P	privilege
OS	beyond the scope
V	Vague and/or ambiguous

EXHIBIT 12

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

PAR PHARMACEUTICAL, INC.,)	
PAR STERILE PRODUCTS, LLC, and)	
ENDO PAR INNOVATION)	
COMPANY, LLC,)	
)	C.A. No. 18-823-CFC
Plaintiffs,)	
)	
v.)	
)	
EAGLE PHARMACEUTICALS INC.,)	
)	
Defendant.)	

DEFENDANT'S DEPOSITION DESIGNATIONS

EXHIBIT 12

Pursuant to Local Rule 16.3(c)(7) and the Court’s Scheduling Order (D.I. 20, 148), Defendant Eagle Pharmaceuticals Inc. (“Eagle” or “Defendant”) respectfully submits herein its list of deposition designations, Plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC (collectively “Plaintiffs”) objections to Eagle’s designations, Plaintiffs’ counter-designations, and Eagle’s objections to such counter-designations. Eagle reserves the right to counter-designate testimony in response to Plaintiffs’ designations.

20552

DEPOSITION DESIGNATIONS OF MICHELLE BONOMI-HUVALA
October 29, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
10	3	10	11		9	21	10	2	
11	2	11	9		12	12	13	3	
11	19	11	24		13	19	14	3	
12	2	12	5		14	8	14	16	S, F
12	7	12	10		15	18	16	6	F
13	5	13	18		24	14	24	24	
14	4	14	7		26	13	27	15	
14	17	14	21		28	4	28	22	
15	13	15	17		29	14	30	2	F, S
16	9	16	14		30	9	30	17	
19	17	19	23		31	7	31	19	
19	25	19	25		32	6	32	23	S, F
20	2	20	13		33	14	33	17	
20	18	20	20		34	11	34	21	NQP
20	24	20	25		35	9	36	5	F, S, R, 403
21	3	21	13		38	5	38	15	F, S
21	15	21	20		39	23	40	20	F, S
21	24	21	25		42	24	43	11	NR
22	2	22	5		43	14	43	17	NR, F, S
22	7	22	18		44	12	44	14	
22	22	22	25		44	17	45	14	NR, F, S
23	2	23	6		45	19	45	22	
23	8	23	10		45	24	45	24	F, S
24	2	24	10		46	4	46	22	F, S
24	12	24	13		47	7	47	11	F, S
24	25	24	25		48	15	49	2	F, S
25	2	25	8		50	23	51	8	
25	10	25	20		51	13	51	20	
26	8	26	10		55	18	56	17	F, S
26	12	26	12		62	20	63	9	F, S
28	23	28	25		63	20	63	23	
29	2	29	12		63	25	64	19	NR, F, S
30	20	30	22		66	20	67	2	F, S, R, 403, 32, AF
30	24	30	25		67	20	67	24	NR, F, S, R, 403, 32, AF
31	2	31	6		92	13	92	18	

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DEPOSITION DESIGNATIONS OF MICHELLE BONOMI-HUALA
October 29, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
31	20	31	24		92	20	92	25	F, S
32	3	32	4		93	17	93	21	F, S
33	2	33	13		94	19	95	7	FORM, R, 403, 32
33	19	33	25		95	9	96	20	FORM, R, 403, 32, F, S
34	2	34	10		96	23	97	6	F, S, R, 403, 32
					97	8	97	10	
34	22	34	25						NQP, NA, R, 403, F, S, 32
35	2	35	8	602/LOF	97	24	98	3	FORM, R, 403, 32, F, S
36	6	36	22		98	6	98	13	FORM, R, 403, 32, F, S
36	25	36	25		98	17	99	11	FORM, R, 403, 32, F, S
37	13	37	23		99	15	99	18	FORM, R, 403, 32, F, S
37	25	37	25		99	21	100	9	FORM, R, 403, 32, F, S
38	2	38	4		100	11	100	11	FORM, R, 403, 32, F, S
38	18	38	25		100	16	101	2	FORM, R, 403, 32, F, S
39	2	39	10		101	5	101	5	FORM, R, 403, 32, F, S
44	7	44	11		101	7	101	18	FORM, R, 403, 32, F, S
45	15	45	18		101	21	102	2	FORM, R, 403, 32, F, S
45	25	45	25		102	7	102	8	FORM, R, 403, 32, F, S
46	2	46	3		102	10	102	21	FORM, R, 403, 32, F, S
46	24	46	25		102	24	102	24	FORM, R, 403, 32, F, S
					103	3	103	5	
47	2	47	6						F, S, 32, R, 403
48	6	48	14		103	7	103	13	FORM, R, 403, 32, F, S
49	3	49	10		103	16	103	25	FORM, R, 403, 32, F, S
49	13	49	19		104	4	104	15	FORM, R, 403, 32, F, S
49	21	49	21		104	18	104	19	FORM, R, 403, 32, F, S
49	24	49	25		105	7	105	20	F, S, 32, R, 403
50	2	50	6	602/LOF, AA, MC	106	2	106	7	F, S, 32, R, 403
50	9	50	20		109	6	109	18	F, S, 32, R, 403
51	9	51	12		110	2	110	14	F, S, 32, R, 403
54	5	54	19		110	16	111	8	F, S, 32, R, 403
56	18	56	25		111	22	112	13	F, S, 32, R, 403
57	2	57	13		112	17	112	21	FORM, R, 403, 32, F, S
58	2	58	5		112	24	112	24	FORM, R, 403, 32, F, S
58	7	58	13						
59	3	59	5						
59	8	59	11						
60	7	60	10						

DEPOSITION DESIGNATIONS OF MICHELLE BONOMI-HUVALA
October 29, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
60	25	60	25						
61	2	61	6						
61	8	61	14						
61	16	61	22						
61	24	61	25						
62	3	62	3						
62	9	62	12						
62	14	62	18						
65	7	65	10						
65	12	65	12						
68	17	68	20	602/LOF, AA, MC					
68	24	68	24						
73	13	73	17						
73	20	73	24						
74	15	74	18						
74	20	74	24						
75	3	75	15						
75	17	75	24						
76	2	76	2						
81	5	81	10	602/LOF, AA, MC, V/incomplete					
91	13	91	17						
91	25	91	25						
92	2	92	2						
92	4	92	9						
92	11	92	11						
93	4	93	16						
93	24	93	25						
94	2	94	5						
106	11	106	25						
107	2	107	19						
107	21	107	25						
108	2	108	3						
108	5	108	25	AA, MC					
109	2	109	2						
109	19	109	23						
111	10	111	16						

DEPOSITION DESIGNATIONS OF BRIAN BOESCH
September 13, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
12	20	12	23		46	7	47	7	R, 403, 32
37	11	37	16	602, LOF	52	13	52	18	R, 403, 32
37	19	37	23		53	4	53	18	R, 403, 32
37	25	37	25		56	4	56	11	R, 403, 32
38	3	38	7		56	13	56	15	R, 403, 32
38	9	38	11	602, LOF, 701, 702	59	3	59	10	R, 403, 32
38	14	38	18	602, LOF, 701, 702	59	13	59	24	R, 403, 32
38	20	38	21	401, 402, 403, 602, LOF	63	24	64	3	R, 403, 32
38	24	38	25	401, 402, 403, 602, LOF	77	21	77	25	R, 403, 32
39	2	39	2	401, 402, 403, 602, LOF	80	23	81	9	R, 403, 32
126	22	126	25	No testimony designated	90	20	91	16	R, 403, 32, F, S
127	13	127	22	801, 802	91	19	91	19	R, 403, 32, F, S
128	2	128	3	801, 802	107	22	108	25	R, 403, 32
128	5	128	23	602, LOF, 801, 802	111	4	111	16	R, 403, 32
129	2	129	10	602, LOF, 801, 802	115	19	115	23	R, 403, 32
129	12	129	14	602, LOF, 801, 802	116	3	116	15	R, 403, 32
130	16	130	18	No testimony designated	117	5	117	23	R, 403, 32
130	20	130	25		125	18	125	21	
138	20	138	23		127	3	127	8	F, S
139	24	139	25	602, LOF	146	3	146	5	R, 403, 32, F, S
140	2	140	2	602, LOF	146	8	146	10	R, 403, 32, F, S
140	5	140	5	602, LOF	146	12	146	17	R, 403, 32, F, S
141	23	141	25	401, 402, 403, 602, LOF, 801, 802, V	146	24	146	25	R, 403, F, S
142	2	142	5	401, 402, 403, 602, LOF, 801, 802, V	147	4	147	13	R, 403, F, S
142	8	142	10	401, 402, 403, 602, LOF, 801, 802, V	150	15	150	16	R, 403
142	12	142	15	401, 402, 403, 801, 802	150	19	150	23	R, 403
142	19	142	22	602, LOF	151	20	151	21	R, 403
142	24	142	25	602, LOF	151	24	152	5	R, 403
143	2	143	4	602, LOF	153	4	153	11	R, 403, 32, F, S
143	10	143	15		169	18	169	19	R, 403, F, S, LAY
144	7	144	8	401, 402, 403, 602, LOF	169	22	169	23	R, 403, F, S, LAY
144	11	144	13	401, 402, 403, 602, LOF	169	25	170	2	R, 403, F, S, LAY
144	15	144	18	401, 402, 403, 602, LOF	170	5	170	5	R, 403, F, S, LAY
145	16	145	18	401, 402, 403, 602, LOF	170	7	170	7	R, 403, F, S, LAY
145	21	145	24	401, 402, 403, 602, LOF	170	10	170	20	R, 403, F, S, LAY, INC
146	18	146	23		180	13	180	22	R, 403, 32, F, S

DEPOSITION DESIGNATIONS OF BRIAN BOESCH
September 13, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
148	7	148	8	401, 402, 403, 602, LOF	180	25	181	4	R, 403, 32, F, S
148	11	148	15	401, 402, 403, 602, LOF, 801, 802	181	9	181	10	R, 403, 32, F, S
148	18	148	18	401, 402, 403, 602, LOF, 801, 802	181	12	181	17	R, 403, 32, F, S
150	5	150	8	401, 402, 403, 602, LOF	185	23	185	24	NQP, NA
150	12	150	14		186	16	186	20	F, S
150	25	150	25	401, 402, 403, 602, LOF	210	3	210	7	R, 403, F, S, LAY
151	2	151	2	401, 402, 403, 602, LOF	210	10	210	15	R, 403, F, S, LAY
151	5	151	7	401, 402, 403, 602, LOF	216	18	216	19	R, 403, 32, F, S
151	17	151	19		216	22	216	22	R, 403, 32, F, S
152	14	152	16	401, 402, 403, 602, LOF	250	18	250	23	
152	19	152	22	401, 402, 403, 602, LOF	253	19	254	3	R, 403, 32
162	16	162	18	401, 402, 403, 602, LOF, 701, 702	256	24	257	5	R, 403, 32
162	21	162	25	401, 402, 403, 602, LOF, 701, 702	257	7	257	13	R, 403, 32
163	2	163	3	401, 402, 403, 602, LOF, 701, 702	257	15	257	17	R, 403, 32
170	22	170	25	602, LOF					
171	4	171	4	602, LOF					
186	25	186	25	602, LOF					
187	2	187	3	602, LOF					
187	6	187	17	602, LOF					
187	19	187	22	602, LOF					
187	25	187	25	602, LOF					
188	2	188	3	602, LOF					
196	13	196	16	V					
204	21	204	25						
205	2	205	5	401, 402, 403, 602, LOF, 701, 702					
205	8	205	14	401, 402, 403, 602, LOF, 701, 702					
205	16	205	16	401, 402, 403, 602, LOF, 701, 702					
205	19	205	20	401, 402, 403, 602, LOF, 701, 702					
205	22	205	25	401, 402, 403, 602, LOF					
206	4	206	6						
206	8	206	9	401, 402, 403, 602, LOF					
206	12	206	25	401, 402, 403, 602, LOF					
207	3	207	5	401, 402, 403, 602, LOF, 701, 702, V					
207	8	207	16	401, 402, 403, 602, LOF, 701, 702, V					
207	22	207	25	401, 402, 403					
208	2	208	12	401, 402, 403					

DEPOSITION DESIGNATIONS OF BRIAN BOESCH
September 13, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
209	3	209	7	401, 402, 403, 602, LOF V					
209	11	209	17	401, 402, 403, 602, LOF V					
210	17	210	23	401, 402, 403, 602, LOF, C, V					
211	2	211	2	401, 402, 403, 602, LOF, C, V					
211	6	211	16	401, 402, 403, V					
221	22	221	23	401, 402, 403, 602, LOF					
222	2	222	5	401, 402, 403, 602, LOF					
222	7	222	9	401, 402, 403, 602, LOF, 701, 702					
222	13	222	15	401, 402, 403, 602, LOF, 701, 702					
250	24	250	25	401, 402, 403, 602, LOF, V, C					
251	2	251	12	401, 402, 403, 602, LOF, V, C					
251	15	251	17	401, 402, 403, 602, LOF, V, C					
251	19	251	23	401, 402, 403, 602, LOF, V, C					

DEPOSITION DESIGNATIONS OF CARLA ENGLISH
September 18, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations*	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
9	17	9	19		9	20	9	21	R, 403, 32
10	17	10	22		18	12	18	16	R, 403, 32
63	3	63	23		18	22	19	2	R, 403, 32
64	11	64	13		23	9	23	12	R, 403, 32
64	15	64	15		23	17	23	20	R, 403, 32, F, S
70	22	70	25		24	24	25	3	R, 403, 32, F, S
71	15	71	15		63	24	64	7	NA, C, INC, R, 403
75	9	75	15		64	17	64	19	R, 403, 32
75	24	75	25		71	2	72	6	NQP, NA, C, 32, R, 403
76	2	76	2		82	25	83	3	NQP, NA, C, 32, R, 403
79	19	79	25		83	9	84	14	F, S, 32, R, 403
80	2	80	4		158	2	158	4	F, S, 32, R, 403
80	23	80	25		158	6	158	8	F, S, 32, R, 403
81	5	81	5		159	24	160	3	F, S, 32, R, 403
82	21	82	24		160	5	160	7	F, S, 32, R, 403
85	18	85	25		161	25	162	4	F, S, 32, R, 403
86	2	86	2		162	6	162	9	F, S, 32, R, 403
140	13	140	23		163	10	163	13	F, S, 32, R, 403
140	24	140	25		163	15	163	17	F, S, 32, R, 403
141	2	141	2		168	2	168	4	F, S, 32, R, 403
141	11	141	23		168	6	168	11	F, S, 32, R, 403
155	12	155	25		172	18	172	19	F, S, 32, R, 403
156	2	156	2		172	22	172	25	F, S, 32, R, 403
156	4	156	8		199	3	199	20	F, S, LAY, R, 403, 32
156	14	156	25		201	3	201	5	F, S, LAY, R, 403 , 32
157	3	157	8		202	18	202	22	F, S, LAY, R, 403 , 32
157	10	157	13		202	25	203	6	F, S, LAY, R, 403 , 32
158	10	158	25	OS, 801-802, 602/LOF	219	4	219	10	F, S, R, 403
159	1	159	7	OS, 801-802, 602/LOF	219	13	219	24	F, S, R, 403
160	19	160	25		220	19	220	21	NQP, NA, C, 32, R, 403
161	2	161	4		282	20	283	20	F, S, R, 403
162	24	162	25		283	23	284	3	F, S, R, 403
163	2	163	9		284	11	284	15	F, S, R, 403
165	23	165	25		284	18	285	5	F, S, R, 403
166	2	166	15		285	7	285	11	F, S, R, 403
166	24	166	25		290	5	290	8	F, S, R, 403

DEPOSITION DESIGNATIONS OF CARLA ENGLISH
September 18, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations*	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
167	2	167	10		290	11	290	25	F, S, R, 403
167	19	167	25		318	24	319	11	F, S, R, 403, 32
169	19	169	25		320	12	320	24	F, S, R, 403, 32
170	2	170	7						
170	18	170	25						
171	2	171	21						
173	22	173	25						
174	2	174	2						
177	17	177	25						
178	2	178	10						
178	25	178	25	OS, 801-802, 602/LOF					
179	2	179	2	OS, 801-802, 602/LOF					
179	5	179	7						
200	9	200	25						
201	2	201	2						
217	21	217	25						
218	2	218	25						
219	2	219	3						
219	25	219	25						
220	2	220	18						
220	23	220	25						
221	2	221	5						
221	8	221	20						
221	22	221	24						
222	2	222	8	602/LOF					
222	11	222	14						
222	17	222	19	602/LOF					
222	21	222	22						
223	10	223	13						
223	16	223	20						
223	22	223	25	OS, 801-802					
224	2	224	2	OS, 801-802					
224	4	224	5						
282	9	282	19						
286	7	286	14						
287	5	287	23						

DEPOSITION DESIGNATIONS OF CARLA ENGLISH
September 18, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations*	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
291	22	291	25						
292	2	292	4						
319	12	319	25	OS, 801-802, 602/LOF					
320	2	320	2	OS, 801-802, 602/LOF					
320	7	320	7						
320	9	320	11						
*Par objects to all designated testimony for this witness outside the scope of the testimony Par agreed to provide in response to Eagle's 30(b)(6) deposition notice pursuant to Fed. R. Evid. 801, 802, and 804, and Fed. R. Civ. P. 45 as the witness is within the subpoena power of the District of Delaware and Eagle has not demonstrated the witness is unavailable.									

Exhibit

DEPOSITION DESIGNATIONS OF VINAYAGAM KANNAN

September 10, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations*	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
14	8	14	11		48	25	48	25	R, 32, 403
29	24	29	25		49	2	49	7	R, 32, 403
30	2	30	3		74	10	74	25	R, 403
35	15	35	24	602/LOF	75	2	75	25	R, 403
36	4	36	25		76	2	76	2	R, 403
37	2	37	8	602/LOF	118	16	118	21	C, NQP, NA, INC
38	11	38	24		152	19	152	25	H, 32, R, 403
46	4	46	11	401/402, 602/LOF, 801-802	153	2	153	25	H, 32, R, 403
46	14	46	25	401/402, 602/LOF, 801-802	154	23	154	25	H, 32, R, 403, F, S
47	2	47	7	401/402, 602/LOF	155	2	155	25	H, 32, R, 403, F, S
47	9	47	10	401/402, 602/LOF	156	2	156	25	H, 32, R, 403, F, S
47	12	47	23	401/402, 602/LOF	157	2	157	22	H, 32, R, 403, F, S
49	19	49	22	602/LOF	217	16	217	20	H, R, F, 403, S
50	8	50	11	602/LOF	217	22	217	25	H, R, F, 403, S
50	13	50	15	602/LOF	218	2	218	3	H, R, F, 403, S
51	14	51	20		226	2	226	12	INC, R, F, 403, S, LAY
52	3	52	7	602/LOF	226	20	226	25	R, F, 403, S
52	13	52	19	602/LOF	227	2	227	21	R, F, 403, S
70	6	70	25	602/LOF	235	4	235	25	H, C, F, R, 32, 403, LAY
71	2	71	2		236	2	236	5	H, C, F, R, 32, 403, LAY
71	6	71	16		250	5	250	12	R, 403, 32
71	19	71	25		255	2	255	4	R, 403, 32
72	2	72	20		255	7	255	8	R, 403, 32
73	4	73	14		255	10	255	12	R, 403, 32
76	3	76	13	401/402, 403	255	15	255	18	R, 403, 32
81	2	81	3	No testimony	255	20	255	25	R, 403, 32
83	12	83	18	801-802	256	2	256	25	R, 403, 32, F, S
84	2	84	11	401/402, 403	257	2	257	7	R, 403, 32
84	13	84	15	401/402, 403	271	24	271	25	
84	17	84	20	401/402, 403, 602/LOF	272	2	272	23	
84	22	84	24	401/402, 403, 602/LOF	272	25	272	25	
85	3	85	7	401/402, 403, 602/LOF	273	2	273	8	
85	17	85	25	401/402, 403, 602/LOF, 801-802	274	2	274	11	
86	2	86	7	401/402, 403, 602/LOF, 801-802	274	13	274	21	
86	12	86	20	401/402, 403, 602/LOF, 801-802	274	24	274	25	
93	6	93	25	401/402, 403, 602/LOF, 701/702, 801-802	275	2	275	14	
94	2	94	11	401/402, 403, 602/LOF, 701/702, 801-802	275	16	275	25	

DEPOSITION DESIGNATIONS OF VINAYAGAM KANNAN
September 10, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations*	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
94	23	94	25	401/402, 403, 602/LOF, 701/702, 801-802	276	2	276	13	
95	2	95	2	401/402, 403, 602/LOF, 701/702, 801-802	284	3	284	11	C, 32, R, 403
95	4	95	6	401/402, 403, 602/LOF, 701/702, 801-802	287	2	287	8	F, S, 32, R, 403, LAY
95	8	95	22	401/402, 403, 602/LOF, 701/702, 801-802	287	10	287	14	F, S, 32, R, 403, LAY
95	24	95	25	401/402, 403, 602/LOF, 701/702, 801-802	287	16	287	25	LAY, R, 403,32
96	3	96	5	401/402, 403, 602/LOF, 701/702, 801-802	288	2	288	7	LAY, R, 403,32
96	7	96	8	401/402, 403, 602/LOF, 701/702, 801-802	293	7	293	24	NQP, INC, F, S, R, 403,32
96	11	96	19	401/402, 403, 602/LOF, 701/702, 801-802	297	4	297	25	FORM, 32, F, S, R, 403
97	17	97	19	401/402, 403, 602/LOF, 701/702	298	2	298	5	FORM, 32, F, S, R, 403
97	22	97	24	401/402, 403, 602/LOF, 701/702	298	8	298	13	FORM, 32, F, S, R, 403, LAY
98	3	98	6	401/402, 403, 602/LOF, 701/702, 801-802	298	15	298	25	H, FORM, 32, F, S, R, 403
98	8	98	11	401/402, 403, 602/LOF, 701/702, 801-802	299	2	299	16	H, FORM, 32, F, S, R, 403
98	13	98	20	401/402, 403, 602/LOF, 701/702, 801-802	299	19	299	21	H, 32, F, S, R, 403
99	3	99	6	401/402, 403, 602/LOF, 701/702	299	23	299	25	H, 32, F, S, R, 403
99	9	99	10	401/402, 403, 602/LOF, 701/702	300	3	300	11	H, 32, FORM, F, S, R, 403
99	12	99	24	401/402, 403, 602/LOF, 801-802	300	14	300	17	H, 32, FORM, F, S, R, 403
101	10	101	25	401/402, 403, 602/LOF, 801-802	300	19	300	24	H, 32, FORM, F, S, R, 403
102	2	102	2	401/402, 403, 602/LOF, 801-802	301	3	301	6	H, 32, FORM, F, S, R, 403
105	21	105	23	401/402, 403, 602/LOF, 801-802	301	8	301	18	H, 32, F, S, R, 403
106	3	106	9	401/402, 403, 602/LOF, 801-802					
107	7	107	10	401/402, 403, 602/LOF, 801-802					
107	14	107	15	401/402, 403, 602/LOF, 801-802					
107	17	107	24	401/402, 403, 602/LOF, 801-802					
108	3	108	3	401/402, 403, 602/LOF, 801-802					
108	16	108	24	401/402, 403, 602/LOF, 801-802					
109	3	109	4	401/402, 403, 602/LOF, 801-802					
116	9	116	14	401/402, 403, 602/LOF					
116	19	116	25	401/402, 403, 602/LOF					
117	5	117	10						

DEPOSITION DESIGNATIONS OF VINAYAGAM KANNAN
September 10, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations*	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
118	12	118	15	401/402, 403, 602/LOF					
118	22	118	24	401/402, 403, 602/LOF					
125	15	125	25	401/402, 403, 602/LOF					
126	2	126	6	401/402, 403, 602/LOF					
127	16	127	25	401/402, 403, 602/LOF					
128	2	128	5	401/402, 403, 602/LOF					
128	8	128	9	401/402, 403, 602/LOF					
128	11	128	14	401/402, 403, 602/LOF					
128	17	128	18	401/402, 403, 602/LOF					
128	20	128	25	401/402, 403, 602/LOF					
129	2	129	4	401/402, 403, 602/LOF					
129	23	129	25	401/402, 403, 602/LOF, 1006, AA					
130	2	130	2	401/402, 403, 602/LOF, 1006, AA					
130	5	130	7	401/402, 403, 602/LOF, 1006, AA					
130	9	130	21	401/402, 403, 602/LOF					
131	2	131	14	401/402, 403, 602/LOF, 701/702					
131	17	131	22	401/402, 403, 602/LOF, 701/702					
132	7	132	25	401/402, 403, 602/LOF					
133	2	133	9	401/402, 403, 602/LOF					
133	12	133	13	401/402, 403, 602/LOF					
133	15	133	22	401/402, 403, 602/LOF					
134	23	134	25						
135	2	135	9	401/402, 403, 602/LOF					
136	11	136	13	401/402, 403, 602/LOF					
136	15	136	15	401/402, 403, 602/LOF					
137	11	137	17						
138	11	138	16	401/402, 403, 602/LOF					
139	10	139	14	401/402, 403, 602/LOF					
139	18	139	25	401/402, 403, 602/LOF					
140	2	140	25	401/402, 403, 602/LOF					
141	2	141	4	401/402, 403, 602/LOF					
141	24	141	25	401/402, 403, 602/LOF					
142	2	142	4	401/402, 403, 602/LOF					
142	8	142	24	602/LOF, 801-802					
143	8	143	12	602/LOF, 801-802					
145	6	145	10	602/LOF, 801-802					
145	13	145	15	602/LOF, 801-802					
145	17	145	24	602/LOF, 801-802					
146	3	146	3	602/LOF, 801-802					
146	14	146	19	602/LOF, 801-802					

DEPOSITION DESIGNATIONS OF VINAYAGAM KANNAN
September 10, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations*	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
147	10	147	25	401/402, 403, 602/LOF, 801-802					
148	2	148	25	401/402, 403, 602/LOF, 801-802					
149	2	149	18	401/402, 403, 602/LOF, 801-802					
149	20	149	20	401/402, 403, 602/LOF, 801-802					
152	3	152	15	401/402, 403, 602/LOF					
158	17	158	20	401/402, 403, 602/LOF					
158	23	158	23	401/402, 403, 602/LOF					
159	5	159	18						
159	21	159	25	401/402, 403, 602/LOF					
160	2	160	18	401/402, 403, 602/LOF					
162	2	162	7	401/402, 403, 602/LOF					
162	14	162	25	401/402, 403, 602/LOF					
163	2	163	10	401/402, 403, 602/LOF					
163	16	163	25	401/402, 403, 602/LOF					
164	2	164	17	401/402, 403, 602/LOF					
164	20	164	22	401/402, 403, 602/LOF					
164	24	164	25	401/402, 403, 602/LOF					
165	2	165	7	401/402, 403, 602/LOF					
165	23	165	25	401/402, 403, 602/LOF					
166	2	166	2	401/402, 403, 602/LOF					
166	4	166	7	401/402, 403, 602/LOF					
166	9	166	14	401/402, 403, 602/LOF					
168	19	168	23	401/402, 403, 602/LOF, 701/702					
169	2	169	8	401/402, 403, 602/LOF, 701/702					
169	10	169	14	401/402, 403, 602/LOF, 701/702					
169	16	169	22	401/402, 403, 602/LOF, 701/702					
171	12	171	18	401/402, 403, 602/LOF, 701/702					
171	20	171	25	401/402, 403, 602/LOF, 701/702					
172	2	172	3	401/402, 403, 602/LOF, 701/702					
186	15	186	25	401/402, 403, 602/LOF					
187	6	187	11	401/402, 403, 602/LOF					
187	22	187	25	401/402, 403, 602/LOF					
188	3	188	4	401/402, 403, 602/LOF					
188	6	188	9	401/402, 403, 602/LOF					
188	11	188	12	401/402, 403, 602/LOF					
188	14	188	22	401/402, 403, 602/LOF					
189	10	189	25	401/402, 403, 602/LOF, 701/702					
190	2	190	4	401/402, 403, 602/LOF, 701/702					
190	7	190	15	401/402, 403, 602/LOF, 701/702					
191	17	191	21	401/402, 403, 602/LOF					

DEPOSITION DESIGNATIONS OF VINAYAGAM KANNAN
September 10, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations*	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
191	23	191	23	401/402, 403, 602/LOF					
191	25	191	25	401/402, 403, 602/LOF					
192	2	192	12	401/402, 403, 602/LOF, 701/702, C					
192	16	192	16	401/402, 403, 602/LOF, 701/702, C					
192	18	192	23	401/402, 403, 602/LOF, 701/702, C					
192	25	192	25	401/402, 403, 602/LOF, 701/702, C					
193	2	193	7	401/402, 403, 602/LOF, 701/702, C					
193	11	193	11	401/402, 403, 602/LOF, 701/702, C					
193	13	193	14	401/402, 403, 602/LOF, 701/702, C					
193	21	193	25	401/402, 403, 602/LOF, 801-802					
194	2	194	13	401/402, 403, 602/LOF, 801-802, AA, P					
194	16	194	24	401/402, 403, AA, P					
195	3	195	8	401/402, 403, AA, P					
195	13	195	15	401/402, 403, P					
196	10	196	15	401/402, 403, AA, P					
196	16	196	18	401/402, 403, AA, P					
196	20	196	25	401/402, 403, AA, P					
197	2	197	7	401/402, 403, AA, P					
197	8	197	10	401/402, 403, AA, P					
197	12	197	16	401/402, 403, AA, P					
198	5	198	9	401/402, 403, AA, P					
198	13	198	16	401/402, 403, P					
199	3	199	5	401/402, 403, AA, P					
199	6	199	7	401/402, 403, AA, P					
199	25	199	25	401/402, 403					
200	2	200	6	401/402, 403					
208	17	208	23	401/402, 403, AA, P					
208	24	208	25	401/402, 403, AA, P					
209	2	209	2	401/402, 403, AA, P					
209	4	209	9	401/402, 403, AA, P					
209	10	209	11	401/402, 403, AA, P					
210	8	210	10	401/402, 403, AA, P					
210	11	210	15	401/402, 403, AA, P					
210	18	210	20	401/402, 403, AA, P					
210	24	210	25						
211	2	211	25	602/LOF					
212	2	212	12	602/LOF					
212	24	212	25	401/402, 403					
213	2	213	12	401/402, 403, 602/LOF, 701/702					
213	17	213	25	602/LOF					

Exhibit

DEPOSITION DESIGNATIONS OF VINAYAGAM KANNAN

September 10, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations*	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
214	2	214	3	602/LOF					
214	14	214	25	401/402, 403, 602/LOF, 701/702					
215	2	215	8	602/LOF					
215	10	215	13	602/LOF					
215	15	215	25	602/LOF					
216	2	216	3	602/LOF					
218	9	218	21	602/LOF					
221	13	221	24	401/402, 403, 602/LOF, 701/702, AA, P					
221	25	221	25	401/402, 403, 602/LOF, AA, P					
222	2	222	3	401/402, 403, 602/LOF, AA, P					
222	2	222	3	401/402, 403, 602/LOF, AA, P					
222	5	222	10	401/402, 403, 602/LOF, AA, P					
222	11	222	12	401/402, 403, 602/LOF, AA, P					
222	15	222	19	401/402, 403, 602/LOF					
224	3	224	25	602/LOF, 701/702					
225	2	225	3	602/LOF, 701/702					
225	6	225	8	602/LOF, 701/702					
225	14	225	21	602/LOF					
227	22	227	25	401/402, 403, 602/LOF, 701/702					
228	2	228	25	401/402, 403, 602/LOF, 701/702					
231	21	231	25	602/LOF, 701/702					
232	2	232	2	602/LOF, 701/702					
232	5	232	10	602/LOF, 701/702					
232	12	232	25						
233	2	233	7						
234	15	234	25	401/402, 403, 602/LOF, 701/702					
235	2	235	4	401/402, 403					
236	19	236	25	401/402, 403					
237	2	237	25	401/402, 403					
238	2	238	6	401/402, 403, 801/802					
238	10	238	25	401/402, 403, 801/802					
239	2	239	25	401/402, 403, 801/802					
240	2	240	4	401/402, 403, 801/802					
240	13	240	16	401/402, 403, 602/LOF					
240	18	240	18	401/402, 403, 602/LOF					
240	22	240	25						
241	2	241	9	602/LOF					
241	16	241	22	401/402, 403					
242	15	242	22	401/402, 403, 602/LOF					
242	25	242	25	401/402, 403, 602/LOF					

Exhibit 2

DEPOSITION DESIGNATIONS OF VINAYAGAM KANNAN

September 10, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations*	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
243	3	243	13	401/402, 403, 602/LOF					
243	16	243	25	401/402, 403, 602/LOF					
244	2	244	4	401/402, 403, 602/LOF					
244	16	244	18	401/402, 403, 602/LOF					
244	20	244	21	401/402, 403, 602/LOF					
244	23	244	25	401/402, 403, 602/LOF					
245	2	245	21	401/402, 403, 602/LOF					
246	3	246	25	401/402, 403					
247	2	247	25	401/402, 403					
248	2	248	10	401/402, 403					
248	13	248	15	401/402, 403					
248	17	248	19	401/402, 403, 602/LOF					
248	22	248	23	401/402, 403, 602/LOF					
249	20	249	25	106, 401/402, 403, 602/LOF, AA, NR, V					
252	3	252	19	401/402, 403, 602/LOF, Legal					
252	22	252	22	401/402, 403, 602/LOF, Legal					
252	24	252	25						
253	2	253	5						
253	12	253	25	401/402, 403, 602/LOF, Legal					
254	2	254	25	401/402, 403, 602/LOF, Legal					
257	8	257	25	401/402, 403, 602/LOF, AA, MC, Legal					
258	2	258	4	401/402, 403, 602/LOF, AA, MC, Legal					
258	10	258	13	401/402, 403, 602/LOF, AA, MC, Legal					
258	16	258	18	401/402, 403, 602/LOF, AA, MC, Legal					
258	20	258	25	401/402, 403, 602/LOF, AA, MC, Legal					
259	2	259	2	401/402, 403, 602/LOF, AA, MC, Legal					
259	5	259	13	401/402, 403, 602/LOF, AA, MC, Legal					
259	15	259	22	401/402, 403, 602/LOF, AA, MC, Legal					
259	25	259	25	401/402, 403, 602/LOF, AA, MC, Legal					
260	2	260	6	401/402, 403, 602/LOF, AA, MC, Legal					
260	8	260	11	401/402, 403, 602/LOF, AA, MC, Legal					
260	13	260	16	401/402, 403, 602/LOF, AA, MC, Legal					
260	18	260	19	401/402, 403, 602/LOF, AA, MC, Legal					
260	22	260	25	401/402, 403, 602/LOF, AA, MC, Legal					
261	2	261	2	401/402, 403, 602/LOF, AA, MC, Legal					
261	4	261	7	401/402, 403, 602/LOF, AA, MC, Legal					
261	9	261	11	401/402, 403, 602/LOF, AA, MC, Legal					
261	13	261	17	401/402, 403, 602/LOF, AA, MC, Legal					
261	20	261	25	401/402, 403, 602/LOF, AA, MC, Legal					
262	6	262	25	401/402, 403, 602/LOF, AA, MC, Legal					

DEPOSITION DESIGNATIONS OF VINAYAGAM KANNAN
September 10, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations*	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
263	4	263	5	401/402, 403, 602/LOF, AA, MC, Legal					
263	7	263	10	401/402, 403, 602/LOF, AA, MC, Legal					
263	13	263	17	401/402, 403, 602/LOF, AA, MC, Legal					
263	21	263	25	401/402, 403, 602/LOF, AA, MC, Legal					
264	11	264	13	401/402, 403, 602/LOF, AA, MC, Legal					
264	16	264	16	401/402, 403, 602/LOF, AA, MC, Legal					
264	20	264	25	602/LOF, 801/802					
265	2	265	9	602/LOF, 801/802					
265	20	265	25	602/LOF, 801/802					
266	2	266	24	401/402, 403, 602/LOF, 801/802, AA, MC, Legal					
267	3	267	4	401/402, 403, 602/LOF, 801/802, AA, MC, Legal					
267	14	267	19						
267	21	267	24	401/402, 403, 602/LOF, 801/802, AA, MC, Legal					
268	3	268	3	401/402, 403, 602/LOF, 801/802, AA, MC, Legal					
268	5	268	13	401/402, 403, 602/LOF, 801/802, AA, MC, Legal					
268	16	268	17	401/402, 403, 602/LOF, 801/802, AA, MC, Legal					
268	19	268	23	401/402, 403, 602/LOF, 801/802, AA, MC, Legal					
269	2	269	3	401/402, 403, 602/LOF, 801/802, AA, MC, Legal					
269	5	269	16	401/402, 403, 602/LOF, AA, MC, P					
269	18	269	22	401/402, 403, 602/LOF, AA, MC, P					
269	23	269	25	401/402, 403, 602/LOF, AA, MC, P					
270	2	270	2	401/402, 403, 602/LOF, AA, MC, P					
270	4	270	9	401/402, 403, 602/LOF, AA, Legal					
270	12	270	15	401/402, 403, 602/LOF, AA, Legal					
270	17	270	20	401/402, 403, 602/LOF, AA, Legal					
270	24	270	25	401/402, 403					
271	2	271	23	401/402, 403					
273	14	273	25	401/402, 403					
276	15	276	22	401/402, 403, 602/LOF					
282	6	282	11	401/402, 403, 602/LOF					
282	17	282	25	401/402, 403, 602/LOF					
283	2	283	8	401/402, 403, 602/LOF					

DEPOSITION DESIGNATIONS OF VINAYAGAM KANNAN
September 10, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations*	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
283	21	283	25	401/402, 403, 602/LOF					
284	2	284	2	401/402, 403, 602/LOF					
288	8	288	25	401/402, 403, 602/LOF					
289	2	289	14	401/402, 403, 602/LOF, 701/702					
289	16	289	18	401/402, 403, 602/LOF, 701/702					
289	24	289	25						
290	2	290	17	602/LOF					
291	9	291	25	401/402, 403, 602/LOF					
292	2	292	25	401/402, 403, 602/LOF					
293	2	293	7	401/402, 403, 602/LOF					
293	25	293	25	401/402, 403, 602/LOF					
294	2	294	25	401/402, 403, 602/LOF, 701/702, C					
295	2	295	22	401/402, 403, 602/LOF, 701/702, AA, P					
295	23	295	25	401/402, 403, 602/LOF, AA, P					
296	3	296	7	401/402, 403, 602/LOF, AA, P					
296	8	296	10	401/402, 403, 602/LOF, AA, P					

*Par objects to all designated testimony for this witness pursuant to Fed. R. Evid. 801, 802, and 804, and Fed. R. Civ. P. 45 as the witness is within the subpoena power of the District of Delaware and Eagle has not demonstrated the witness is unavailable.

Exhibit 3

DEPOSITION DESIGNATIONS OF CRAIG KENESKY

October 3, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
11	24	11	25		10	18	11	11	C, R, 403, NQP, NA , 32
12	2	12	4		12	5	12	10	R, 403, 32
16	3	16	12		77	4	77	19	F, S, R, 403, 32
16	17	16	20		108	19	108	25	F, S, R, 403, 32
17	3	17	9		109	7	109	13	F, S, R, 403, 32
23	25	23	25		109	19	109	22	F, S, R, 403, 32
24	2	24	3						
24	6	24	6						
24	8	24	13	P, AA, 401, 403					
24	14	24	14	P, AA, 401, 403					
24	15	24	19	P, AA, 401, 403					
26	22	26	25	P, AA, 401, 403					
27	2	27	2	P, AA, 401, 403					
27	3	27	6	P, AA, 401, 403					
27	8	27	14	P, AA, 401, 403					
32	24	32	25						
33	2	33	3						
33	22	33	25						
34	2	34	10						
34	17	34	25						
35	2	35	14						
37	6	37	15						
43	14	43	22	P, AA, 401-403					
43	24	43	25	P, AA, 401-403					
44	2	44	7	P, AA, 401-403					
51	22	51	25						
52	2	52	25						
53	2	53	25						
54	2	54	3						
54	13	54	25						
55	2	55	11						
56	9	56	18						
57	9	57	25						
58	2	58	5						
58	15	58	25						
59	2	59	24						
60	23	60	25						
61	2	61	25						
62	2	62	3						
62	23	62	25						

DEPOSITION DESIGNATIONS OF CRAIG KENESKY
October 3, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
63	2	63	20						
64	14	64	25						
65	2	65	18						
65	20	65	20						
65	22	65	25						
66	2	66	25						
67	2	67	7						
68	17	68	25						
69	2	69	2						
69	25	69	25	P, AA, 401-403					
70	2	70	8	P, AA, 401-403					
70	9	70	9	P, AA, 401-403					
70	11	70	17	P, AA, 401-403					
70	18	70	18	P, AA, 401-403					
70	20	70	25	P, AA, 401-403					
71	2	71	2	P, AA, 401-403					
72	3	72	21						
75	17	75	25						
76	2	76	6						
77	20	77	25	602/LOF, 701/702					
78	4	78	6	602/LOF, 701/702					
78	7	78	7	602/LOF, 701/702					
79	6	79	9	602/LOF, 401-403, 701/702					
79	13	79	16	602/LOF, 401-403, 701/702					
80	10	80	16						
80	20	80	21						
82	17	82	22	602/LOF, 401-403, 701/702					
82	24	82	25	602/LOF, 401-403, 701/702					
83	2	83	11	602/LOF, 401-403, 701/702					
83	13	83	15						
83	18	83	18						
83	20	83	24	P, AA, 401-403					
84	3	84	10	P, AA, 401-403					
84	12	84	18	P, AA, 401-403					
84	19	84	20	P, AA, 401-403					
84	22	84	25	P, AA, 401-403					
85	2	85	6	P, AA, 401-403					
85	19	85	25						
86	2	86	8						
86	20	86	25						

EXHIBIT
DEPOSITION DESIGNATIONS OF CRAIG KENESKY
October 3, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
87	2	87	14						
87	21	87	25						
88	2	88	6						
88	15	88	17						
88	20	88	20						
88	22	88	25						
89	20	89	25						
90	2	90	24						
91	10	91	17						
91	19	91	20						
93	9	93	21						
94	5	94	7						
94	9	94	16						
95	7	95	11						
95	13	95	14						
97	11	97	22						
98	14	98	21						
99	3	99	5						
99	19	99	23						
100	2	100	4						
100	9	100	13						
101	25	101	25						
102	2	102	9						
102	12	102	13						
102	15	102	18						
102	21	102	23						
102	25	102	25						
103	2	103	25						
104	2	104	8						
104	21	104	25						
106	13	106	20						
106	23	106	24						
107	3	107	13	P, AA, 401-403 107:10-13					
107	14	107	14	P, AA, 401-403					
107	16	107	20	P, AA, 401-403					
107	22	107	25	P, AA, 401-403 107:22-24					
108	2	108	7	P, 602/LOF, AA, 401-403 107:25-108:7					

Exhibit 2

DEPOSITION DESIGNATIONS OF CRAIG KENESKY

October 3, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
108	10	108	14	P, 602/LOF, AA, 401-403					
110	13	110	20	AA, Misstates the law					
111	3	111	4	AA, Misstates the law					
111	6	111	14	AA, Misstates the law					
111	20	111	21	AA, Misstates the law					
111	23	111	25						
112	2	112	5						
112	11	112	12						
113	6	113	15	AA, Misstates the law					
113	19	113	20	AA, Misstates the law					
115	21	115	25	AA, Misstates the law, 401-403, 701/702					
116	2	116	5	AA, Misstates the law, 401-403					
116	11	116	14	AA, Misstates the law, 401-403					
117	3	117	19	AA, Misstates the law, 601/LOF, 701/702					
117	22	117	25	AA, Misstates the law, 601/LOF, 701/702					
119	19	119	25						
120	7	120	7						
120	9	120	16	P, 401-403, AA					
120	18	120	24	P, 401-403, AA					
121	3	121	25	AA, P, 401-403 121:3-16					
122	2	122	13						
122	15	122	17	401-403, AA, P					
122	20	122	25	401-403, AA, P					
123	2	123	9	401-403, AA, P					
123	13	123	21	401-403, AA, P					
123	23	123	25	401-403, AA, P					
124	2	124	17	401-403, AA, P					
125	18	125	25						
126	6	126	6						
126	8	126	25	401-403, AA, P					
127	2	127	3	401-403, AA, P					
127	5	127	15	401-403, AA, P					
127	17	127	25						
128	2	128	9						
128	17	128	17						
128	19	128	25	401-403, AA, P					

DEPOSITION DESIGNATIONS OF CRAIG KENESKY
October 3, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
129	2	129	3	401-403, AA, P					
129	5	129	11	401-403, AA, P					
129	13	129	22	401-403, AA, P					
129	24	129	25						
130	2	130	12						
130	20	130	20						
130	22	130	25	401-403, AA, P					
131	2	131	6	401-403, AA, P					
131	8	131	17	401-403, AA, P					
131	19	131	25	401-403, AA, P					
132	2	132	6	401-403, AA, P					
132	8	132	20						
133	3	133	8	401-403, AA, P					
133	11	133	12	401-403, AA, P					
133	14	133	18	401-403, AA, P					
133	20	133	23	401-403, AA, P					
133	25	133	25	401-403, AA, P					
134	2	134	9	401-403, AA, P					
135	19	135	23						
136	3	136	4						
136	6	136	18	401-403, AA, P					
136	20	136	25	401-403, AA, P					
137	2	137	4	401-403, AA, P					
137	6	137	16	401-403, AA, P					
137	18	137	20	401-403, AA, P					
137	24	137	25	401-403, AA, P					
138	2	138	9	401-403, AA, P					
139	12	139	25						
140	4	140	4						
140	13	140	25						
141	2	141	3						
141	15	141	25						
142	2	142	18						
142	20	142	21						
142	23	142	25						
143	2	143	25						
144	2	144	7	401-403, AA, P 144:4-25					
144	11	144	15	401-403, AA, P 144:4-25					

Exhibit 2

DEPOSITION DESIGNATIONS OF CRAIG KENESKY

October 3, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
144	17	144	25	401-403, AA, P 144:4-25					
145	2	145	3	401-403, AA, P					
145	4	145	5	401-403, AA, P					
146	4	146	11						
146	16	146	17						
146	21	146	25						
147	2	147	13						
147	15	147	15						
147	24	147	25	401-403, AA, P					
148	2	148	3	401-403, AA, P					
148	6	148	17	401-403, AA, P					
149	15	149	19						
149	21	149	21						
149	23	149	25						
150	2	150	4						
150	7	150	8						
150	10	150	18	401-403, AA, P					
150	20	150	25						
151	2	151	8						
151	10	151	10						
151	12	151	20	401-403, AA, P					
151	22	151	25	401-403, AA, P					
152	2	152	15	401-403, AA, P					
152	17	152	24	401-403, AA, P					
153	3	153	11	401-403, AA, P					
154	18	154	25						
155	2	155	14						
156	4	156	25						
157	2	157	2						
157	5	157	10						
158	22	158	25						
159	2	159	5						
159	9	159	12						
159	20	159	25	AA, 401-403, 602/LOF, 701/702					
160	6	160	8	AA, 401-403, 602/LOF, 701/702					
161	8	161	14	AA, 401-403, 602/LOF, 701/702					
161	19	161	23	AA, 401-403, 602/LOF, 701/702					
161	25	161	25	AA, 602/LOF, 701/702					
162	2	162	17	AA, 602/LOF, 701/702					

Exhibit 9

DEPOSITION DESIGNATIONS OF CRAIG KENESKY

October 3, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
164	3	164	9	AA, 401-403, 602/LOF, 701/702					
164	12	164	16	AA, 401-403, 602/LOF, 701/702					
165	23	165	25	AA, 401-403, 602/LOF, 701/702					
166	2	166	6	AA, 401-403, 602/LOF, 701/702					
166	10	166	14	AA, 401-403, 602/LOF, 701/702					
166	16	166	22	AA, 401-403, 602/LOF, 701/702					
167	2	167	6	AA, 401-403, 602/LOF, 701/702					
167	8	167	13						
167	20	167	20						
168	18	168	23	AA, 401-403, 602/LOF, 701/702					
169	4	169	8	AA, 401-403, 602/LOF, 701/702					
169	10	169	12	AA, 401-403, 602/LOF, 701/702					
169	17	169	18	AA, 401-403, 602/LOF, 701/702					
171	5	171	12						
171	15	171	18						
171	23	171	25						
172	2	172	5						
172	7	172	9						
173	12	173	16						
173	19	173	20						
174	17	174	23	AA, 401-403, 602/LOF, 701/702					
175	3	175	5	AA, 401-403, 602/LOF, 701/702					
175	7	175	11	AA, 401-403, 602/LOF, 701/702					
175	15	175	16	AA, 401-403, 602/LOF, 701/702					
197	9	197	13						
201	10	201	24						
202	4	202	6						
204	23	204	25						
205	2	205	4						
205	9	205	25						
206	2	206	2						
206	21	206	25						
207	2	207	2						
207	9	207	17						
208	8	208	11						

DEPOSITION DESIGNATIONS OF MATTHEW KENNEY
October 18, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
7	25	7	25		8	4	8	5	R, 403, 32
8	2	8	3		11	18	11	25	F, S, R, 403
9	4	9	25		12	2	12	5	F, S, R, 403
10	2	10	4		18	14	18	25	R, NQP, 403
17	14	17	23	401, 402, 403, V	19	2	19	9	R, 403, 32
17	25	17	25	401, 402, 403, V	20	9	20	11	
18	2	18	2	401, 402, 403, V	20	24	20	25	F, S, R, 403
18	4	18	7	401, 402, 403, V	23	21	23	24	F, S, R, 403
18	9	18	10	401, 402, 403, V	24	11	24	13	F, S, R, 403
19	22	19	25	401, 402, 403	27	10	27	14	F, S, R, 403
20	2	20	5	401, 402, 403	28	20	28	22	F, S, R, 403
20	16	20	22	401, 402, 403, 602, LOF, 801, 802, 901	29	15	29	18	F, S, R, 403
21	6	21	12	401, 402, 403, 801, 802	42	15	42	24	F, S, R, 403
23	25	23	25	401, 402, 403, 602, LOF, 901	43	3	43	4	F, S, R, 403
24	2	24	4	401, 402, 403, 602, LOF, 901	43	14	43	18	F, S, R, 403
24	6	24	10	401, 402, 403, 602, LOF, 901	45	6	45	24	LAY, F, R, 403, S
28	6	28	10	401, 402, 403, 602, LOF, 901	46	15	46	21	LAY, F, R, 403, S
28	14	28	18	602, LOF, 801, 802, V	47	16	47	24	H, NR, F, S, 403
29	7	29	9	602, LOF, 801, 802, V	48	2	48	4	H, NR, F, S, 403
29	11	29	13	602, LOF, 801, 802, V	56	22	56	25	32, F, S, R, 403
30	21	30	25	401, 402, 403, 602, LOF, V	58	20	58	24	F, S, R, 403
31	2	31	2	401, 402, 403, 602, LOF, V	70	18	70	25	LAY, F, R, 403, S, 32
31	12	31	25	401, 402, 403, 602, LOF, 901	71	2	71	5	LAY, F, R, 403, S, 32
32	2	32	23	401, 402, 403, 602, LOF	77	4	77	18	LAY, F, S, R, 403, 32
33	11	33	17	401, 402, 403	78	6	78	9	LAY, F, S, R, 403, 32
34	20	34	23	401, 402, 403, 602, LOF	78	12	78	13	LAY, F, S, R, 403, 32
34	25	34	25	401, 402, 403, 602, LOF	78	15	78	17	LAY, F, S, R, 403, 32
35	2	35	3	401, 402, 403, 602, LOF	80	5	80	10	F, S, R, 403
36	20	36	24	401, 402, 403	80	23	80	25	F, S, R, 403
38	16	38	25	401, 402, 403	81	2	81	4	F, S, R, 403
39	2	39	4	401, 402, 403	81	12	81	18	F, S, R, 403
39	14	39	17	401, 402, 403, V	81	25	81	25	F, S, R, 403
39	19	39	20	401, 402, 403, V	82	2	82	15	F, S, R, 403
39	22	39	25	401, 402, 403	82	18	82	19	F, S, R, 403
40	2	40	25	401, 402, 403	86	5	86	13	LAY, F, S, R, 403, 32
41	2	41	25	401, 402, 403	86	16	86	20	LAY, F, S, R, 403, 32

DEPOSITION DESIGNATIONS OF MATTHEW KENNEY
October 18, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
42	2	42	14	401, 402, 403	86	22	86	25	LAY, F, S, R, 403, 32
43	6	43	9	401, 402, 403, 602, LOF	87	2	87	3	LAY, F, S, R, 403, 32
43	11	43	12	401, 402, 403, 602, LOF	87	13	87	25	LAY, F, S, R, 403,
44	5	44	25	401, 402, 403, 602, LOF	88	2	88	5	LAY, F, S, R, 403,
45	2	45	2		89	8	89	13	LAY, F, S, R, 403, 32
46	22	46	24	106, 602, LOF	89	16	89	18	LAY, F, S, R, 403, 32
46	25	46	25	106, 602, LOF	89	20	89	21	LAY, F, S, R, 403, 32
47	2	47	3	106, 602, LOF	100	21	100	24	F, S, R, 403
47	11	47	14	106, 602, LOF	102	10	102	25	F, S, R, 403
48	6	48	14	106, 602, LOF	103	2	103	3	F, S, R, 403
48	17	48	19	106, 602, LOF	103	17	103	20	F, S, R, 403
48	25	48	25		104	17	104	19	F, S, R, 403
49	2	49	18	401, 402, 403, 701, 702	104	21	104	22	F, S, R, 403
49	21	49	22	401, 402, 403, 701, 702	105	9	105	11	H, F, S, R, 403
50	11	50	17	401, 402, 403, 701, 702, V	109	20	109	21	F, S, R, 403
50	20	50	22	401, 402, 403, 701, 702, V	109	23	109	24	F, S, R, 403
51	5	51	15	401, 402, 403, 701, 702	111	14	111	17	F, S, R, 403, 32
55	3	55	16		118	4	118	5	LAY, F, S, R, 403
56	15	56	21	401, 402, 403	118	7	118	7	LAY, F, S, R, 403
58	25	58	25	401, 402, 403	118	9	118	25	LAY, F, S, R, 403
59	2	59	9	401, 402, 403, 602, LOF	119	2	119	2	LAY, F, S, R, 403
59	12	59	13	401, 402, 403, 602, LOF	119	5	119	5	LAY, F, S, R, 403
59	19	59	24	106, 401, 402, 403, 602, LOF	119	8	119	13	LAY, F, S, R, 403
62	21	62	25	401, 402, 403, 602, LOF	121	13	121	16	LAY, F, S, R, 403
63	2	63	10	401, 402, 403, 602, LOF	121	19	121	20	LAY, F, S, R, 403
64	5	64	13	401, 402, 403, 602, LOF	122	15	122	17	LAY, F, S, R, 403
74	8	74	18	401, 402, 403, 602, LOF	122	20	122	22	LAY, F, S, R, 403
74	20	74	21	401, 402, 403, 602, LOF	123	13	123	19	LAY, F, S, R, 403
74	23	74	25	401, 402, 403, 602, LOF, C	123	22	123	24	LAY, F, S, R, 403
75	2	75	3	401, 402, 403, 602, LOF, C	124	2	124	5	LAY, F, S, R, 403
75	5	75	5	401, 402, 403, 602, LOF, C	124	7	124	8	LAY, F, S, R, 403
75	7	75	11						
				401, 402, 403, 602, LOF	124	25	124	25	F, S, R, 403
75	13	75	14	401, 402, 403, 602, LOF	125	2	125	7	F, S, R, 403
75	24	75	25	602, LOF	126	22	126	23	LAY, 32, F, S, R, 403
76	2	76	2	602, LOF	127	2	127	3	LAY, 32, F, S, R, 403
76	4	76	5	602, LOF	127	5	127	11	LAY, 32, F, S, R, 403

DEPOSITION DESIGNATIONS OF MATTHEW KENNEY
October 18, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
76	16	76	18	401, 402, 403, 602, LOF, 701, 702	127	13	127	16	LAY, 32, F, S, R, 403
76	22	76	25	401, 402, 403, 602, LOF, 701, 702	129	2	129	5	LAY, F, S, R, 403
77	2	77	2	401, 402, 403, 602, LOF, 701, 702	130	16	130	20	LAY, F, S, R, 403
78	24	78	25	401, 402, 403, 701, 702, Legal, V	150	24	150	25	LAY, 32, H, F, S, R, 403
79	2	79	2	401, 402, 403, 701, 702, Legal, V	151	2	151	22	LAY, 32, H, F, S, R, 403
79	5	79	7	401, 402, 403, 701, 702, Legal, V	153	5	153	12	LAY, 32, H, F, S, R, 403
79	9	79	12	401, 402, 403, 701, 702, Legal, V	153	15	153	18	LAY, 32, H, F, S, R, 403
79	13	79	17	401, 402, 403, 602, LOF, 701, 702, Legal, V	153	20	153	25	LAY, 32, H, F, S, R, 403
79	19	79	19	401, 402, 403, 602, LOF, 701, 702, Legal, V	154	2	154	21	LAY, 32, H, F, S, R, 403
79	23	79	25	401, 402, 403, 602, LOF, 901	154	24	154	25	LAY, 32, H, F, S, R, 403
80	2	80	3	401, 402, 403, 602, LOF, 901	155	3	155	5	LAY, 32, H, F, S, R, 403
80	11	80	22	401, 402, 403	156	5	156	12	LAY, 32, H, F, S, R, 403
81	8	81	11	401, 402, 403	156	15	156	17	LAY, 32, H, F, S, R, 403
81	19	81	24	401, 402, 403, 602, LOF	156	19	156	21	LAY, 32, F, S, R, 403
85	13	85	17	401, 402, 403, 602, LOF, 701, 702	156	24	156	25	LAY, 32, F, S, R, 403
85	20	85	21	401, 402, 403, 602, LOF, 701, 702	157	2	157	3	LAY, 32, F, S, R, 403
87	4	87	12	401, 402, 403	157	5	157	6	LAY, 32, F, S, R, 403
97	8	97	18	401, 402, 403	157	9	157	11	LAY, 32, F, S, R, 403
99	22	99	24		157	13	157	25	LAY, 32, F, S, R, 403
100	5	100	11		158	2	158	20	LAY, 32, F, S, R, 403
101	3	101	21	401, 402, 403, 602, LOF, 901, 902	159	6	159	16	LAY, 32, F, S, R, 403
103	4	103	5		159	19	159	19	LAY, 32, F, S, R, 403
103	6	103	9		159	21	160	5	LAY, 32, F, S, R, 403, NR
104	4	104	16	602, LOF	160	7	160	9	LAY, 32, F, S, R, 403
107	14	107	17	602, LOF, 701, 702	160	11	160	17	LAY, 32, F, S, R, 403
107	20	107	22	602, LOF, 701, 702	160	19	160	21	LAY, 32, F, S, R, 403
108	6	108	9	602, LOF, 701, 702	160	23	161	22	LAY, 32, F, S, R, 403
108	12	108	14	602, LOF, 701, 702	163	2	163	4	LAY, 32, F, S, R, 403
108	16	108	25	602, LOF, 701, 702, MC, AA	163	7	163	7	LAY, 32, F, S, R, 403
109	2	109	13	602, LOF, 701, 702, MC, AA	169	16	169	20	LAY, 32, F, S, R, 403
109	15	109	19	602, LOF	169	23	169	23	LAY, 32, F, S, R, 403
110	4	110	17	106, 701, 702	172	20	172	24	LAY, 32, F, S, R, 403
110	20	110	22	701, 702	173	4	173	7	LAY, 32, F, S, R, 403
110	24	110	25	C, V	174	23	174	24	LAY, 32, F, S, R, 403
111	2	111	4	C, V	182	13	182	18	F, S, R, 32, 403
111	18	111	18		182	20	182	25	F, S, R, 32, 403
111	19	111	25		183	2	183	7	F, S, R, 32, 403
112	2	112	7		183	21	183	23	F, S, R, 32, 403

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DEPOSITION DESIGNATIONS OF MATTHEW KENNEY

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Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
112	9	112	11		183	25	183	25	F, S, R, 32, 403
114	16	114	19	602, LOF, 701, 702	184	2	184	2	F, S, R, 32, 403
114	22	114	24	602, LOF, 701, 702	184	4	184	7	F, S, R, 32, 403
115	2	115	6	602, LOF, 701, 702	184	9	184	11	F, S, R, 32, 403
116	11	116	16	602, LOF, 701, 702	184	13	184	20	F, S, R, 32, 403
116	19	116	23	602, LOF, 701, 702	184	22	184	25	F, S, R, 32, 403
117	3	117	5	602, LOF, 701, 702	185	2	185	7	F, S, R, 32, 403
117	8	117	9	602, LOF, 701, 702	185	10	185	11	F, S, R, 32, 403
117	11	117	13	602, LOF, 701, 702	185	13	185	25	LAY, F, S, R, 32, 403
117	15	117	17	602, LOF, 701, 702	186	2	186	7	LAY, F, S, R, 32, 403
117	19	117	21	602, LOF, 701, 702	186	9	186	18	LAY, F, S, R, 32, 403
117	23	117	25	602, LOF, 701, 702	187	7	187	10	LAY, F, S, R, 32, 403
118	2	118	2	602, LOF, 701, 702	187	13	187	20	LAY, F, S, R, 32, 403
119	15	119	22		188	3	188	5	LAY, F, S, R, 32, 403
121	7	121	8	701, 702	188	8	188	11	LAY, F, S, R, 32, 403
121	9	121	12	701, 702	209	14	209	19	32, F, S, R, 403
123	2	123	7	106, 602, LOF, 701, 702	209	21	209	25	32, F, S, R, 403
123	10	123	11	106, 602, LOF, 701, 702	210	2	210	7	32, F, S, R, 403
124	12	124	16		210	9	210	10	32, F, S, R, 403
124	18	124	24		210	12	210	16	32, F, S, R, 403
125	8	125	8	401, 402, 403	210	24	210	25	32, F, S, R, 403
125	9	125	17	401, 402, 403	211	2	211	15	32, F, S, R, 403
127	18	127	21	401, 402, 403, 701, 702	211	18	211	25	32, F, S, R, 403
127	23	127	25	401, 402, 403, 701, 702	212	2	212	4	32, F, S, R, 403
128	8	128	19	401, 402, 403, 701, 702	213	10	213	13	32, F, S, R, 403
128	22	128	24	401, 402, 403, 701, 702	213	15	213	15	32, F, S, R, 403
129	6	129	20	401, 402, 403	213	17	213	20	32, F, S, R, 403
129	25	129	25	401, 402, 403, 701, 702	214	16	214	20	32, F, S, R, 403
130	2	130	10	401, 402, 403, 701, 702	215	11	215	15	
130	13	130	14	401, 402, 403, 701, 702	216	11	216	18	
132	14	132	25	401, 402, 403	218	23	218	25	32, F, S, R, 403
133	2	133	2	401, 402, 403	219	2	219	8	32, F, S, R, 403
133	4	133	6	401, 402, 403	219	10	219	12	32, F, S, R, 403
133	8	133	20	401, 402, 403	223	24	223	25	F, S, R, 403
133	23	133	24	401, 402, 403	224	2	224	25	F, S, R, 403
145	25	145	25	602, LOF	225	2	225	7	F, S, R, 403
146	2	146	9	602, LOF	226	25	226	25	F, S, R, 403
147	9	147	25	401, 402, 403	227	2	227	3	F, S, R, 403
148	2	148	5	401, 402, 403	227	6	227	7	F, S, R, 403
161	23	161	24	401, 402, 403, 602, LOF	227	9	227	11	F, S, R, 403

DEPOSITION DESIGNATIONS OF MATTHEW KENNEY
October 18, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
162	2	162	13	401, 402, 403, 602, LOF	227	14	227	15	F, S, R, 403
162	15	162	25	401, 402, 403, 602, LOF, 701, 702	228	19	228	25	32, F, S, R, 403, H
163	22	163	25	401, 402, 403, 602, LOF, 701, 702	229	2	229	25	32, F, S, R, 403, H
164	2	164	8	401, 402, 403, 602, LOF, 701, 702	230	2	230	25	32, F, S, R, 403, C, H
171	13	171	25	401, 402, 403, 602, LOF, 701, 702	231	2	231	2	32, F, S, R, 403, H
172	2	172	6	401, 402, 403, 701, 702	232	7	232	20	F, S, R, 403
172	8	172	9	401, 402, 403, 701, 702	233	10	232	18	F, S, R, 403
172	11	172	19	401, 402, 403	234	3	234	12	F, S, R, 403
173	9	173	11	401, 402, 403, 602, LOF, 701, 702	236	11	236	13	F, S, R, 403
173	14	173	14	401, 402, 403, 602, LOF, 701, 702	236	15	236	21	F, S, R, 403, H, LAY
173	16	173	19	401, 402, 403, 602, LOF, 701, 702	237	11	237	14	F, S, R, 403
173	22	173	25	401, 402, 403, 602, LOF, 701, 702	237	16	237	19	F, S, R, 403
174	2	174	3	401, 402, 403, 602, LOF, 701, 702	241	4	241	6	R, 403, 32
174	5	174	7	401, 402, 403, 602, LOF, 701, 702	241	17	241	18	R, 403, 32
174	10	174	12	401, 402, 403, 602, LOF, 701, 702	241	20	241	24	R, 403, 32
174	16	174	22	401, 402, 403, 602, LOF	244	18	244	20	R, 403, 32
175	2	175	4	401, 402, 403, 602, LOF	244	23	244	25	R, 403, 32
175	7	175	8	401, 402, 403, 602, LOF	255	10	255	12	R, 403, 32
214	24	214	25		258	2	258	4	LAY, F, S, R, 403, 32
215	2	215	4		258	7	258	9	LAY, F, S, R, 403, 32
215	6	215	10		261	20	261	23	LAY, S, R, F, 403, 32
215	23	215	25	V	262	2	262	4	LAY, S, R, F, 403, 32
216	2	216	2	V	262	6	262	13	LAY, S, R, F, 403, 32
217	20	217	25		262	25	262	25	
218	2	218	3		263	2	263	3	32, LAY, R, 403
218	5	218	8		263	5	263	10	32, LAY, R, 403
218	10	218	12		271	21	271	25	32, R, 403, C
219	22	219	25	401, 402, 403, 602, LOF, V	272	7	272	10	32, F, S, H, R, 403
220	2	220	8	401, 402, 403, 602, LOF, V	272	13	272	17	32, F, S, H, R, 403
220	11	220	12	401, 402, 403, 602, LOF, 701, 702, V	272	19	272	19	32, F, S, H, R, 403, FORM
220	16	220	20	401, 402, 403, 602, LOF, 701, 702, V	273	5	273	7	32, F, S, H, R, 403, FORM
220	23	220	25	401, 402, 403, 602, LOF, 701, 702, V	273	9	273	13	32, F, S, H, R, 403, FORM
221	2	221	8	401, 402, 403, 602, LOF, 701, 702, V	273	15	273	25	32, F, S, H, R, 403, FORM
221	10	221	12	401, 402, 403, 602, LOF, 701, 702, V	274	16	274	20	32, F, S, H, R, 403
221	15	221	18	401, 402, 403, 602, LOF, 701, 702, V	274	22	274	25	32, F, S, H, R, 403
221	20	221	23	401, 402, 403, 701, 702	275	2	275	10	32, F, S, H, R, 403
222	2	222	3	401, 402, 403, 701, 702	275	20	275	21	R, 403, 32
222	5	222	8	401, 402, 403, 602, LOF, 701, 702, V	276	25	276	25	LAY, FORM, H, 32, F, S, R, 403
222	11	222	12	401, 402, 403, 602, LOF, 701, 702, V	277	2	277	10	LAY, FORM, H, 32, F, S, R, 403
222	25	222	25		277	21	277	23	LAY, FORM, H, 32, F, S, R, 403

DEPOSITION DESIGNATIONS OF MATTHEW KENNEY
October 18, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
223	2	223	13		277	25	277	25	LAY, FORM, H, 32, F, S, R, 403
225	19	225	25	401, 402, 403	278	2	278	2	LAY, FORM, H, 32, F, S, R, 403
226	2	226	15	401, 402, 403, 701, 702, V	278	4	278	7	LAY, 32, F, S, R, 403
226	18	226	24	401, 402, 403, 701, 702, V	278	15	278	17	R, 403, 32
228	3	228	15	V	278	22	278	25	H, R, 403, 32, F, S
228	16	228	18		279	2	279	8	H, R, 403, 32, F, S
231	6	231	19		279	15	279	21	H, R, 403, 32, F, S
231	24	231	25						
232	2	232	6						
233	3	233	9						
233	19	233	25						
234	2	234	2						
234	13	234	25						
235	2	235	25						
236	2	236	10						
236	23	236	25						
237	2	237	6	V					
237	8	237	9	V					
238	5	238	11						
238	14	238	25	106					
239	2	239	25						
240	2	240	5						
240	7	240	10						
240	12	240	16						
240	21	240	25						
241	2	241	3						
246	3	246	7						
246	9	246	15						
251	16	251	25	401, 402, 403, 602, LOF					
252	2	252	2	401, 402, 403, 602, LOF					
252	4	252	4	401, 402, 403, 602, LOF					
252	22	252	25	401, 402, 403, Legal					
253	2	253	2	401, 402, 403, Legal					
253	6	253	6	401, 402, 403, Legal					
253	25	253	25	401, 402, 403, 602, LOF					
254	2	254	6	401, 402, 403, 602, LOF					
254	8	254	10	401, 402, 403					
254	12	254	16	401, 402, 403, V					
254	18	254	18	401, 402, 403, V					
254	20	254	25	401, 402, 403					

October 18, 2019

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DEPOSITION DESIGNATIONS OF MICHELLE RENNWALD
October 1, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
7	6	7	8		117	21	117	25	F, S, R, 403, 32
60	2	60	15	401/402, 403, 602/LOF	118	2	118	20	F, S, R, 403, 32
60	17	60	19	401/402, 403, 602/LOF	118	24	118	25	F, S, R, 403, 32
197	5	197	10		119	2	119	6	F, S, R, 403, 32
198	5	198	19		119	8	119	16	F, S, R, 403, 32
198	21	198	22		197	11	197	25	F, S, R, 403, 32
199	6	199	8		198	2	198	4	F, S, R, 403, 32
199	10	199	12		198	24	198	25	
199	14	199	15		199	2	199	5	H
199	17	199	18		199	20	199	25	C
200	21	200	25	401/402, 403, 602/LOF, OS	200	2	200	7	F, S, R, 403, 32
201	1	201	8	401/402, 403, 602/LOF, OS	200	10	200	12	F, S, R, 403, 32
201	10	201	16	401/402, 403, 602/LOF	202	10	202	17	F, S, R, 403, 32, LAY
202	21	202	25	401/402, 403, 602/LOF	213	10	213	15	F, S, R, 403, 32, LAY
203	1	203	13	401/402, 403, 602/LOF, 701/702	214	2	214	25	F, S, R, 403, 32
203	16	203	21	401/402, 403, 602/LOF, 701/702	215	2	215	10	H, F, S, R, 403, 32
203	23	203	25	401/402, 403, 602/LOF, 701/702					
204	2	204	5	401/402, 403, 602/LOF, 701/702					
204	8	204	11	401/402, 403, 602/LOF, 701/702					
204	15	204	23	401/402, 403, 602/LOF, 701/702					
205	2	205	3	401/402, 403, 602/LOF, 701/702					
205	5	205	7	401/402, 403, 602/LOF, 701/702					
205	10	205	12	401/402, 403, 602/LOF, 701/702					
205	14	205	19	401/402, 403, 602/LOF, 701/702					
205	22	205	25	401/402, 403, 602/LOF, 701/702					
206	2	206	3	401/402, 403, 602/LOF, 701/702					
206	5	206	10	401/402, 403, 602/LOF, 701/702					
206	13	206	15	401/402, 403, 602/LOF, 701/702					
206	17	206	24	401/402, 403, 602/LOF, 701/702					
207	2	207	4	401/402, 403					
207	6	207	10	401/402, 403					
207	12	207	18	401/402, 403					
207	20	207	24	401/402, 403, 602/LOF					
208	3	208	3	401/402, 403, 602/LOF					
208	6	208	8	401/402, 403, 602/LOF					
208	10	208	15	401/402, 403, 602/LOF					

DEPOSITION DESIGNATIONS OF RONALD AUNGST
October 3, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
6	13	6	15		6	5	6	12	
8	21	8	25		9	18	10	3	
9	2	9	17		10	17	10	19	Form
10	7	10	11		10	23	11	4	R, 403
21	10	21	25		20	7	21	9	32
22	19	22	25		22	16	22	18	R, 403, 32
23	2	23	5	FRE 602	45	23	46	25	R, 403, 32
23	7	23	12	FRE 602	47	8	48	8	Form, R, 403, 32
45	10	45	22		48	10	48	11	Form, R, 403
51	18	51	21		48	20	48	22	R, 403, 32
51	24	51	25		49	8	51	17	H, R, 403
52	3	52	25		53	9	55	6	Form, H, R, 403, S, 32
53	2	53	8		55	9	55	9	Form, R, 403, S, 32
63	23	63	25	V, NR, FRE 401-403	55	11	55	22	R, 403, S, 32
64	2	64	6	V, NR, FRE 401-403	67	17	68	13	R, 403, S, 32
67	5	67	16	FRE 106, 401-403	85	21	86	2	32
73	3	73	13		87	8	87	11	R, 403, 32
75	25	75	25	FRE 401-403, 602, 701-702	107	18	108	6	Form, R, 403, F, S, 32
76	2	76	19	FRE 401-403, 602, 701-702	108	8	108	8	Form, R, 403, 32
86	3	86	25	FRE 106, 401-403	110	8	110	13	Form, R, 403, F, S, 32
87	2	87	7	FRE 106, 401-403	110	16	110	17	Form, R, 403, F, S, 32
105	7	105	15	FRE 106, 401-403	116	21	117	5	H, R, 403
105	17	105	21	FRE 106, 401-403	119	5	120	15	Form, H, R, 403, 32
105	23	105	25	FRE 106, 401-403	120	17	120	18	Form, H, R, 403, 32
106	2	106	2	FRE 106, 401-403	120	20	122	6	R, 403, F, S, 32
106	7	106	22	FRE 106, 401-403	136	10	137	12	F
107	10	107	17	FRE 106, 401-403, 602, 701-702	137	14	137	20	F
109	16	109	21	NR, FRE 106, 602	142	17	142	23	Form, H, R, 403, F, S
109	24	109	25	NR, FRE 106, 602	171	11	171	23	H
110	2	110	4	NR, FRE 106, 602	214	16	215	25	H, R, 403, 32
111	2	111	9	NR, OS, FRE 106, 401-403, 602	221	18	221	25	32
111	14	111	14	NR, OS, FRE 106, 401-403, 602	223	5	223	5	32
117	6	117	25	FRE 106, 401-403	223	11	224	15	Form, H, R, 403, 32
118	2	118	25	FRE 106, 401-403	224	17	225	9	Form, H, R, 403, 32
119	2	119	4	FRE 106, 401-403	227	11	227	25	R, 403, 32
135	18	135	25	FRE 401-403, 701-702	267	4	267	7	R, 403, 32

Exhibit

DEPOSITION DESIGNATIONS OF RONALD AUNGST

October 3, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
136	2	136	9	FRE 401-403, 701-702	275	6	275	18	32
138	20	138	25	NR, FRE 401-403, 602, 701-702					
139	2	139	3	NR, FRE 401-403, 602, 701-702					
139	6	139	7	NR, FRE 401-403, 602, 701-702					
139	9	139	13	NR, FRE 401-403, 602, 701-702					
139	15	139	25	NR, FRE 401-403, 602, 701-702					
140	2	140	13	NR, FRE 401-403, 602, 701-702					
161	10	161	12	V, FRE 106					
161	14	161	24	V, FRE 106					
162	14	162	25						
163	2	163	25						
164	2	164	4						
167	25	167	25						
168	2	168	16						
170	25	170	25						
171	2	171	4						
178	8	178	13						
193	9	193	17						
198	7	198	22						
207	9	207	19						
207	22	207	25						
208	2	208	13						
214	10	214	15	FRE 106, 401-403					
216	2	216	9						
219	2	219	13						
221	5	221	9	FRE 106, 401-403					
221	11	221	12	FRE 106, 401-403					
221	14	221	17	FRE 106, 401-403					
222	12	222	25						
223	2	223	4						
226	12	226	25						
227	2	227	10						
241	11	241	22						
242	10	242	25						
243	3	243	22						
262	24	262	25						

DEPOSITION DESIGNATIONS OF RONALD AUNGST
October 3, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
263	2	263	25						
266	10	266	25						
267	2	267	3						
267	8	267	25						
268	2	268	6						
268	14	268	18						
268	25	268	25						
269	2	269	9						
270	4	270	19						
271	23	271	25						
272	2	272	4						
275	19	275	25	FRE 106, 401-403					
276	2	276	14	FRE 106, 401-403					

DEPOSITION DESIGNATIONS OF SUKETU SANGHVI
October 11, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations*	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
10	21	10	24		21	3	21	7	R, 403
13	3	13	10		25	10	25	17	H, R, F, 32, 403, S
13	21	13	25		25	22	26	15	32, R, 403
19	22	19	25		30	5	30	7	NQP, R, 403, C, 32
20	2	20	7		31	4	31	9	NQP, R, 403, C, 32
20	9	20	10		39	20	40	7	H, R, F, 403
20	21	20	25	401, 402, 403	44	4	44	9	R, 403
21	2	21	2	401, 402, 403	47	3	47	7	32, NQP, R, 403
26	20	26	24	401, 402, 403, 602, LOF	67	11	67	21	F, S, R, 403
29	15	29	25	801, 802	68	2	68	4	S, F, R, 403
30	2	30	4		78	2	78	8	
30	8	30	17		78	12	78	16	
30	19	30	21		79	12	79	23	32, F, R, S, 403
36	11	36	19	602, LOF	80	2	80	3	32, F, R, S, 403
36	24	36	25		80	9	80	13	32, F, R, S, 403, H
37	2	37	4		80	17	80	25	32, F, R, S, 403, H
37	6	37	8	801, 802	81	8	81	9	32, F, R, S, 403
37	22	37	25	801, 802	81	11	81	25	32, F, R, S, 403, H
38	2	38	16						
				801, 802	85	21	86	2	
39	9	39	19	401, 402, 403, 801, 802	98	18	98	23	F, S, R, 403
43	14	43	25	401, 402, 403, 602, LOF	111	12	111	18	
									32, F, S, R, 403
44	2	44	3	401, 402, 403	113	5	113	12	32, F, S, R, 403
47	8	47	16	106, 602, LOF, V	126	14	126	19	LAY, 32, R, F, 403, S
47	18	47	19	602, LOF, V	126	22	126	24	LAY, 32, R, F, 403, S
47	21	47	25	602, LOF, V	133	2	133	2	
49	25	49	25	602, LOF, 801, 802, 901	135	6	135	12	R, 32, F, 403, NR
50	2	50	9	602, LOF, 801, 802, 901	143	4	143	8	F, S, R, 403
50	11	50	15	602, LOF, 801, 802, 901	147	7	147	13	NR, F, S, R, LAY, 403, 32
52	2	52	6	401, 402, 403, V	147	16	147	17	NR, F, S, R, LAY, 403, 32
52	8	52	10						
				401, 402, 403, V	147	19	148	12	NR, F, S, R, LAY, 403, 32
52	12	52	15	401, 402, 403, V	152	10	152	18	32, LAY, F, S, R, 403
52	17	52	19	401, 402, 403, V	153	19	153	21	NR, F, S, R, LAY, 403, 32
52	21	52	25	801, 802	153	23	154	4	NR, F, S, R, LAY, 403, 32
53	2	53	22	801, 802	154	6	154	8	NR, F, S, R, LAY, 403, 32
54	9	54	25	801, 802	154	15	154	21	R, 403, S, F
55	2	55	3	801, 802	156	24	157	6	

DEPOSITION DESIGNATIONS OF SUKETU SANGHVI
October 11, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations*	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
55	6	55	12	801, 802	159	9	159	15	
55	13	55	25	801, 802	159	18	159	20	R, 403, 32, S, F
56	2	56	2	801, 802	159	23	160	2	R, 403, 32, S, F
57	15	57	25	602, LOF	174	23	175	3	R, 403, 32, S, F
58	2	58	21	602, LOF	175	7	175	10	R, 403, 32, S, F
58	22	58	25		175	13	175	15	R, 403, 32, S, F
59	2	59	25		182	17	183	8	H, 32, R, F, 403
60	2	60	25	401, 402, 403, 701, 702, 801, 802	202	12	202	16	H, 32, R, 403, F
61	2	61	3	401, 402, 403	202	18	202	19	H, 32, R, 403, F
61	18	61	22	602, LOF, 801, 802	202	21	202	24	32, R, 403, F, S
61	25	61	25	602, LOF, V	203	4	203	19	32, R, 403, F, S
62	2	62	6	602, LOF, V	203	22	203	23	32, R, 403, F, S
62	8	62	12	602, LOF, V	206	6	206	9	F, S, R, 403
62	14	62	21	401, 402, 403, 602, LOF	212	22	213	5	32, NR, F, R, 403
62	24	62	25	401, 402, 403, 602, LOF	216	10	216	15	32
63	2	63	3	401, 402, 403, 602, LOF	218	3	218	6	32, F, S, R, 403
63	13	63	20	401, 402, 403, 602, LOF	218	22	219	10	LAY, 32, F, S, R, 403
64	4	64	9	401, 402, 403, 602, LOF	221	8	221	22	LAY, 32, F, S, R, 403
64	23	64	25		229	9	229	13	32, R, F, S, 403, LAY
65	2	65	12	602, LOF	229	16	229	20	32, R, F, S, 403, LAY
65	15	65	17	602, LOF					
65	19	65	25						
66	11	66	22	602, LOF					
67	22	67	25	106, 602, LOF					
68	10	68	25	801, 802					
69	2	69	3	801, 802					
69	16	69	20	LOF, 801, 802					
70	12	70	16	602, LOF, OS					
70	21	70	25	602, LOF, OS					
71	2	71	7	OS					
71	19	71	25	602, LOF, MC, OS					
72	2	72	5	602, LOF, OS					
72	10	72	14	602, LOF, OS, V					
72	20	72	22	602, LOF, OS					
73	9	73	20	602, LOF, OS					
73	23	73	25	602, LOF, OS					

Exhibit

DEPOSITION DESIGNATIONS OF SUKETU SANGHVI

October 11, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations*	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
74	2	74	3	602, LOF, OS					
74	5	74	8	403, V					
75	7	75	12	602, LOF, OS					
75	18	75	25	602, LOF, OS					
76	2	76	6	602, LOF, OS					
76	9	76	10	602, LOF, OS					
76	12	76	25	602, LOF, OS					
77	2	77	19	403, OS					
78	18	78	25	401, 402, 403, 602, LOF, OS					
79	2	79	2	401, 402, 403, OS					
79	4	79	6	401, 402, 403, OS					
82	9	82	24	OS					
84	14	84	16	701, 702, OS, V					
84	18	84	19	701, 702, OS, V					
84	21	84	25	701, 702, OS					
85	2	85	7	701, 702, OS					
85	12	85	20	701, 702, OS					
91	3	91	7	OS, V					
91	15	91	17	OS					
91	19	91	24	401, 402, 403, OS, C					
92	3	92	4	401, 402, 403, OS, C					
92	6	92	8						
92	16	92	24	OS					
93	3	93	5	OS					
94	9	94	23	401, 402, 403, 602, LOF, 701, 702, 801, 802, OS					
95	2	95	3	401, 402, 403, 602, LOF, 701, 702, 801, 802, OS					
95	5	95	9	401, 402, 403, 602, LOF, 701, 702, 801, 802, OS					
95	11	95	14	401, 402, 403, 602, LOF, 701, 702, OS					
95	16	95	17	401, 402, 403, 602, LOF, 701, 702, OS					
95	19	95	25						
96	2	96	13	401, 402, 403, 602, LOF, 701, 702, OS					
96	16	96	17	401, 402, 403, 602, LOF, 701, 702, OS					
96	19	96	21	401, 402, 403, 602, LOF, 701, 702, OS					
97	7	97	11	401, 402, 403, 701, 702					
97	13	97	15	401, 402, 403, 701, 702					
97	17	97	18	401, 402, 403, 701, 702					
97	20	97	22	401, 402, 403, 701, 702					

Exhibit

DEPOSITION DESIGNATIONS OF SUKETU SANGHVI

October 11, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations*	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
97	24	97	25	401, 402, 403, 701, 702					
98	2	98	2	401, 402, 403, 701, 702					
98	5	98	6	401, 402, 403, 701, 702					
98	15	98	17	106, 602, LOF					
98	24	98	25						
99	2	99	5	401, 402, 403					
99	10	99	25	401, 402, 403					
100	2	100	6	401, 402, 403					
101	23	101	25	401, 402, 403, 602, LOF, 701, 702, OS					
102	2	102	3	401, 402, 403, 602, LOF, 701, 702, OS					
102	7	102	10	401, 402, 403, 602, LOF, 701, 702, OS					
102	12	102	18	401, 402, 403, 602, LOF, 701, 702, OS					
102	21	102	22	401, 402, 403, 602, LOF, 701, 702, OS					
103	3	103	7	401, 402, 403, 602, LOF, 701, 702, OS					
103	10	103	13	401, 402, 403, 602, LOF, 701, 702, OS					
103	19	103	22						
104	2	104	20	401, 402, 403					
105	20	105	24	401, 402, 403, 602, LOF, 701, 702, OS					
106	3	106	6	401, 402, 403, 602, LOF, 701, 702, OS					
106	8	106	14	401, 402, 403					
108	14	108	20	401, 402, 403, 602, LOF, 701, 702, OS					
108	23	108	25	401, 402, 403, 602, LOF, 701, 702, OS					
109	2	109	2	401, 402, 403, 602, LOF, 701, 702, OS					
109	4	109	25	401, 402, 403					
110	2	110	2	401, 402, 403					
110	11	110	15	401, 402, 403					
110	17	110	19	401, 402, 403					
111	24	111	25	602, LOF					
112	2	112	8	602, LOF					
112	16	112	21						
113	13	113	16	602, LOF					
113	18	113	19	602, LOF					
113	21	113	25	602, LOF					
114	2	114	25	602, LOF					
115	2	115	3	602, LOF					
115	6	115	7	602, LOF					
115	9	115	11	401, 402, 403, 602, LOF, 701, 702					
115	14	115	18	401, 402, 403, 602, LOF, 701, 702					
115	20	115	25	401, 402, 403, 602, LOF, 701, 702					
116	2	116	11	401, 402, 403, 602, LOF, 701, 702					

DEPOSITION DESIGNATIONS OF SUKETU SANGHVI
October 11, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations*	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
116	14	116	15	401, 402, 403, 602, LOF, 701, 702					
117	16	117	25						
118	3	118	4						
118	6	118	13	401, 402, 403					
118	15	118	20	401, 402, 403					
118	22	118	25	401, 402, 403					
119	3	119	8	401, 402, 403					
119	18	119	25	401, 402, 403, V					
120	3	120	7	401, 402, 403, V					
120	9	120	12	401, 402, 403, V					
121	11	121	20	401, 402, 403, V					
122	9	122	14	401, 402, 403					
123	5	123	13	401, 402, 403, 602, LOF, 701, 702					
123	16	123	18	401, 402, 403, 602, LOF, 701, 702					
123	20	123	23	401, 402, 403, 602, LOF, 701, 702					
124	2	124	4	401, 402, 403, 602, LOF, 701, 702					
127	3	127	6	401, 402, 403, 602, LOF, 701, 702					
127	9	127	12	401, 402, 403, 602, LOF, 701, 702					
127	14	127	18	401, 402, 403, 602, LOF, 701, 702					
127	21	127	24	401, 402, 403, 602, LOF, 701, 702					
128	3	128	11	401, 402, 403, 602, LOF, 701, 702					
128	14	128	15	401, 402, 403, 602, LOF, 701, 702					
128	17	128	20	401, 402, 403, 602, LOF, 701, 702					
128	23	128	24	401, 402, 403, 602, LOF, 701, 702					
129	12	129	16	401, 402, 403, 602, LOF, 701, 702					
129	19	129	21	401, 402, 403, 602, LOF, 701, 702					
129	23	129	24	401, 402, 403, 602, LOF, 701, 702					
130	3	130	5	401, 402, 403, 602, LOF, 701, 702					
130	7	130	15	401, 402, 403, 602, LOF, 701, 702					
130	19	130	21	401, 402, 403, 602, LOF, 701, 702					
130	23	130	25	401, 402, 403, 602, LOF, 701, 702					
131	4	131	5	401, 402, 403, 602, LOF, 701, 702					
131	7	131	18						
131	20	131	21						
132	19	132	22	106, 602, LOF					
132	25	132	25	106, 602, LOF					
137	21	137	25						
138	2	138	10						
138	12	138	13						
138	15	138	24						

Exhibit

DEPOSITION DESIGNATIONS OF SUKETU SANGHVI

October 11, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations*	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
141	7	141	25						
142	2	142	25						
143	2	143	3						
143	12	143	23	401, 402, 403					
144	5	144	14	106, 401, 402, 403					
144	17	144	20	106, 401, 402, 403					
145	9	145	12	401, 402, 403					
145	14	145	16	401, 402, 403					
146	16	146	25	401, 402, 403, 602, LOF, 701, 702					
147	4	147	5	401, 402, 403, 602, LOF, 701, 702					
148	14	148	20	401, 402, 403, 602, LOF, 701, 702					
148	23	148	25	401, 402, 403, 602, LOF, 701, 702					
149	1	149	3	401, 402, 403, 602, LOF, 701, 702					
149	5	149	8	401, 402, 403, 602, LOF, 701, 702					
150	13	150	14	401, 402, 403, 602, LOF, 701, 702					
150	16	150	18	401, 402, 403, 602, LOF, 701, 702					
150	20	150	25	401, 402, 403					
151	2	151	10	401, 402, 403, 602, LOF, 701, 702					
151	13	151	14	401, 402, 403, 602, LOF, 701, 702					
151	16	151	18	401, 402, 403, 602, LOF, 701, 702					
151	21	151	22	401, 402, 403, 602, LOF, 701, 702					
151	24	151	25	401, 402, 403, 602, LOF, 701, 702					
152	2	152	2	401, 402, 403, 602, LOF, 701, 702					
152	4	152	5	401, 402, 403, 602, LOF, 701, 702					
152	7	152	9	401, 402, 403, 602, LOF, 701, 702					
152	19	152	21	401, 402, 403, 602, LOF, 701, 702					
152	23	152	24	401, 402, 403, 602, LOF, 701, 702					
153	3	153	6	401, 402, 403, 602, LOF					
153	8	153	10	401, 402, 403, 602, LOF					
154	9	154	14	401, 402, 403					
155	16	155	20	401, 402, 403, 602, LOF					
155	22	155	24	401, 402, 403, 602, LOF					
156	3	156	6	401, 402, 403, V					
156	8	156	9	401, 402, 403, V					
157	8	157	16	401, 402, 403, V					
157	22	157	25						
158	2	158	7						
158	15	158	20	801, 802					
159	2	159	8	801, 802					
160	4	160	21	401, 402, 403, 602, LOF, 801, 802					

DEPOSITION DESIGNATIONS OF SUKETU SANGHVI
October 11, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations*	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
162	23	162	25	401, 402, 403, 602, LOF, 801, 802					
163	2	163	10	401, 402, 403, 602, LOF, 801, 802					
170	12	170	25	401, 402, 403, 602, LOF, 801, 802					
171	2	171	12	401, 402, 403, 602, LOF, 801, 802					
171	19	171	25	401, 402, 403, 602, LOF, 801, 802					
172	2	172	10	401, 402, 403, 602, LOF, 801, 802					
174	14	174	22	401, 402, 403, 602, LOF					
175	23	175	25	401, 402, 403, 602, LOF					
176	2	176	2	401, 402, 403, 602, LOF					
176	3	176	18	401, 402, 403, 602, LOF					
177	17	177	23	401, 402, 403, 602, LOF					
178	19	178	25	401, 402, 403, 602, LOF					
179	2	179	14	401, 402, 403, 602, LOF					
179	17	179	18	401, 402, 403, 602, LOF					
179	25	179	25	401, 402, 403, 602, LOF					
180	2	180	21	401, 402, 403, 602, LOF					
181	6	181	18	401, 402, 403, 602, LOF, 701, 702, 801, 802					
181	21	181	24	401, 402, 403, 602, LOF, 701, 702, 801, 802					
182	3	182	7	401, 402, 403, 602, LOF, 701, 702					
182	10	182	11	401, 402, 403, 602, LOF, 701, 702					
187	16	187	22	602, LOF					
187	25	187	25	602, LOF					
188	2	188	4	602, LOF					
188	11	188	13	401, 402, 403					
188	18	188	24	401, 402, 403					
203	25	203	25	401, 402, 403					
204	2	204	25	401, 402, 403					
205	2	205	4	401, 402, 403					
205	12	205	25	602, LOF					
206	2	206	5	602, LOF					
209	22	209	25						
210	2	210	25						
211	2	211	12						
211	14	211	25						
212	2	212	16						
212	17	212	21						
213	6	213	24						
214	6	214	9						

DEPOSITION DESIGNATIONS OF SUKETU SANGHVI
October 11, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations*	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
214	12	214	12						
214	15	214	17						
214	19	214	25						
215	2	215	3						
223	7	223	9	401, 402, 403					
223	14	223	16	401, 402, 403					
223	18	223	24	401, 402, 403, 501, 502, AA					
224	3	224	16	401, 402, 403, 501, 502, AA					
224	18	224	25	401, 402, 403, 501, 502, AA					
225	2	225	2	401, 402, 403, 501, 502, AA					
225	23	225	25	401, 402, 403					
226	2	226	2	401, 402, 403					
226	4	226	6	401, 402, 403					
230	20	230	25						
231	2	231	10						
231	21	231	25						
232	2	232	5	701, 702					
232	8	232	11	701, 702					
*Par objects to all designated testimony for this witness outside the scope of the testimony Par agreed to provide in response to Eagle's 30(b)(6) deposition notice pursuant to Fed. R. Evid. 801, 802, and 804, and Fed. R. Civ. P. 45 as the witness is within the subpoena power of the District of Delaware and Eagle has not demonstrated the witness is unavailable.									

DEPOSITION DESIGNATIONS OF SUNIL VANDSE
September 13, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations*	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
10	21	10	23		79	15	79	21	LAY, F, S, R, 403
19	9	19	12		79	24	79	25	LAY, F, S, R, 403
22	7	22	16		80	2	80	4	LAY, F, S, R, 403
22	25	22	25		80	14	80	18	R, F, S, 403, LAY, 32
23	2	23	6		80	21	80	24	NR, R, F, S, 403, LAY, 32
26	9	26	18		84	1	84	11	R, F, S, 403, 32
27	3	27	8		90	3	90	7	F, S, R, 403
35	5	35	20	602/LOF, 701/702	90	10	90	19	F, S, R, 403
35	23	35	25	602/LOF, 701/702	100	6	100	12	R, 403, 32
40	20	40	24		100	14	100	25	R, 403, 32, F, S
42	23	42	25	401/402, 403	101	2	101	8	R, 403, 32, F, S, LAY
43	2	43	5	401/402, 403	101	11	101	12	R, 403, 32, F, S, LAY
43	8	43	10	401/402, 403	101	14	101	16	R, 403, 32, F, S, LAY
44	3	44	13	401/402, 403	103	12	103	25	LAY, F, S, R, 403
46	8	46	11		104	2	104	16	LAY, F, S, R, 403
46	14	46	22		105	13	105	25	LAY, F, S, R, 403
47	3	47	14	401/402, 403	106	2	106	25	LAY, F, S, R, 403
48	4	48	15	401/402, 403	107	4	107	19	C, LAY, F, S, R, 403
50	16	50	16	401/402, 403	109	6	109	14	32, LAY, F, S, R, 403
50	17	50	25	401/402, 403	143	15	143	25	32, R, 403, S, F
51	2	51	2	401/402, 403	144	2	144	9	32, R, 403, S, F
53	3	53	12	401/402, 403	146	14	146	25	LAY, F, S, R, 403
69	4	69	17	401/402, 403	147	2	147	15	LAY, F, S, R, 403
69	20	69	23	401/402, 403	148	15	148	19	LAY, F, S, R, 403
69	25	69	25	401/402, 403	148	22	148	25	LAY, F, S, R, 403
70	2	70	25	401/402, 403	149	2	149	14	LAY, F, S, R, 403
71	2	71	12	401/402, 403	149	17	149	25	LAY, F, S, R, 403
71	15	71	23	602/LOF, 801-802	152	2	152	9	INC, NQP, 32, F, S, R, 403 , LAY
72	17	72	20	401/402, 403, 602/LOF, 801-802	152	12	152	25	32, F, S, R, 403 , LAY
72	23	72	24	401/402, 403, 602/LOF, 801-802	153	2	153	15	32, F, S, R, 403 , LAY
73	6	73	9	401/402, 403, 602/LOF, 801-802	154	18	154	24	32, F, S, R, 403 , LAY
73	15	73	25	401/402, 403, 602/LOF, 801-802	155	3	155	25	32, F, S, R, 403 , LAY
74	12	74	25	401/402, 403, 602/LOF, 801-802	156	2	156	2	32, F, S, R, 403 , LAY
75	2	75	25	401/402, 403, 602/LOF, 801-802	159	17	159	25	
76	2	76	4	401/402, 403, 602/LOF, 801-802	160	2	160	12	
76	8	76	9	401/402, 403, 602/LOF, 801-802	161	11	161	15	32, F, S, R, 403 , LAY

DEPOSITION DESIGNATIONS OF SUNIL VANDSE
September 13, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations*	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
77	24	77	25	401/402, 403, 701/702	161	18	161	23	32, F, S, R, 403 , LAY
78	2	78	8	401/402, 403, 701/702	162	15	162	20	32, F, S, R, 403 , LAY
78	25	78	25	401/402, 403, 701/702	162	22	162	25	32, F, S, R, 403 , LAY
79	2	79	7	401/402, 403, 701/702	163	2	163	2	32, F, S, R, 403 , LAY
79	10	79	13	401/402, 403, 701/702	176	17	176	21	LAY, F, S, R, 403
81	2	81	18	401/402, 403, 602/LOF, 701/702, 801-802	176	24	176	25	LAY, F, S, R, 403
81	21	81	21	401/402, 403, 602/LOF, 701/702, 801-802	177	2	177	7	LAY, F, S, R, 403
81	24	81	25		177	12	177	18	LAY, F, S, R, 403
82	2	82	23		177	21	177	25	LAY, F, S, R, 403
83	2	83	4		178	2	178	6	LAY, F, S, R, 403
85	13	85	16	401/402, 403, 602/LOF	179	17	179	22	LAY, F, S, R, 403
85	19	85	22	401/402, 403, 602/LOF	179	25	179	25	LAY, F, S, R, 403
86	23	86	25	401/402, 403, 602/LOF	180	2	180	23	LAY, F, S, R, 403
87	2	87	19	401/402, 403, 602/LOF	189	20	189	25	LAY, F, S, R, 403
87	23	87	23	401/402, 403, 602/LOF	190	2	190	25	H, LAY, F, S, R, 403
89	17	89	20	401/402, 403, 602/LOF	191	2	191	11	LAY, F, S, R, 403
89	23	89	25	401/402, 403, 602/LOF	202	6	202	25	R, 403, F, S
90	22	90	25	401/402, 403, 602/LOF	203	2	203	3	R, 403, F, S
91	4	91	5	401/402, 403, 602/LOF	206	20	206	25	32, F, S, R, 403
91	8	91	12	401/402, 403, 602/LOF	207	2	207	2	32, F, S, R, 403
91	17	91	25		207	5	207	21	32, F, S, R, 403
92	2	92	9	401/402, 403, 602/LOF	208	2	208	3	32, F, S, R, 403
92	12	92	18	401/402, 403, 602/LOF	210	6	210	9	32, F, S, R, 403 , H, LAY
92	20	92	25	401/402, 403, 602/LOF, 701/702	210	12	210	25	32, F, S, R, 403 , H, LAY
93	4	93	9	401/402, 403, 602/LOF, 701/702	211	2	211	8	32, F, S, R, 403 , H, LAY
93	11	93	21	401/402, 403, 701/702	234	19	234	25	32, F, S, R, 403
94	2	94	7	401/402, 403, 602/LOF, 701/702	235	2	235	17	32, F, S, R, 403
94	10	94	13	401/402, 403, 602/LOF, 701/702	240	19	240	20	F, S, R, 403
94	17	94	25	401/402, 403, 701/702	240	23	240	24	F, S, R, 403
95	2	95	6	401/402, 403, 701/702	241	2	241	8	F, S, R, 403
95	9	95	14	401/402, 403, 701/702	251	22	251	25	F, S, R, 403, LAY
95	18	95	25	401/402, 403, 701/702	252	2	252	6	F, S, R, 403, LAY
96	2	96	13	401/402, 403, 701/702	252	25	252	25	F, S, R, 403, LAY
97	5	97	25	401/402, 403, 701/702	253	2	253	7	F, S, R, 403, LAY

DEPOSITION DESIGNATIONS OF SUNIL VANDSE
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Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations*	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
98	2	98	3	401/402, 403, 701/702	253	10	253	24	F, S, R, 403, LAY
98	6	98	7	401/402, 403, 701/702	254	4	254	15	F, S, R, 403, LAY
98	9	98	17	401/402, 403, 602/LOF, 701/702	270	4	270	9	FORM, F, S, R, 403, LAY
98	20	98	25	401/402, 403, 602/LOF, 701/702	270	13	270	17	FORM, F, S, R, 403, LAY
99	4	99	12	401/402, 403, 602/LOF, 701/702	270	19	270	25	H, LAY, F, S, R, 403
99	14	99	21	401/402, 403, 602/LOF, 701/702	271	2	271	25	H, LAY, F, S, R, 403
99	24	99	25	401/402, 403, 602/LOF, 701/702	272	2	272	24	FORM, H, LAY, F, S, R, 403
100	2	100	4	401/402, 403, 602/LOF, 701/702	273	3	273	4	FORM, H, LAY, F, S, R, 403
102	12	102	16	401/402, 403, 701/702					
102	19	102	20	401/402, 403, 701/702					
102	22	102	25	401/402, 403, 701/702					
103	2	103	2	401/402, 403, 701/702					
103	3	103	11	401/402, 403, 701/702					
104	19	104	24	401/402, 403, 701/702					
105	3	105	5	401/402, 403, 701/702					
105	7	105	12	401/402, 403, 701/702					
112	15	112	17	401/402, 403, 602/LOF, 701/702					
112	20	112	24	401/402, 403, 602/LOF, 701/702					
113	2	113	5	401/402, 403, 602/LOF, 701/702					
113	16	113	23	401/402, 403, 602/LOF					
113	25	113	25	401/402, 403, 602/LOF, 701/702					
114	2	114	6	401/402, 403, 602/LOF, 701/702					
114	9	114	10	401/402, 403, 602/LOF, 701/702					
115	21	115	25						
116	2	116	3						
118	16	118	19						
118	21	118	21						
119	14	119	25	401/402, 403, 602/LOF					
120	3	120	12	401/402, 403, 602/LOF					
122	11	122	25						
123	3	123	13						
124	2	124	14						
125	15	125	25	401/402, 403, 602/LOF, 701/702					
126	2	126	3	401/402, 403, 602/LOF, 701/702					
126	6	126	7	401/402, 403, 602/LOF, 701/702					
127	7	127	25						
128	2	128	9	401/402, 403, 602/LOF, 701/702					
128	12	128	25	401/402, 403, 602/LOF, 701/702					
129	2	129	3	401/402, 403, 602/LOF, 701/702					
129	6	129	9	401/402, 403, 602/LOF, 701/702					

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Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations*	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
130	19	130	25	701/702					
131	2	131	3	701/702					
131	6	131	11	701/702					
131	14	131	22	401/402, 403, 602/LOF, 701/702					
131	24	131	25	401/402, 403, 602/LOF, 701/702					
132	3	132	12	401/402, 403, 602/LOF, 701/702					
132	15	132	19	401/402, 403, 602/LOF, 701/702					
132	21	132	25	401/402, 403, 602/LOF, 701/702					
133	2	133	9	401/402, 403, 602/LOF, 701/702					
133	13	133	24	401/402, 403, 602/LOF, 701/702					
134	2	134	3	401/402, 403, 602/LOF, 701/702					
134	5	134	8	401/402, 403, 602/LOF, 701/702					
142	17	142	25	401/402, 403, 602/LOF, 701/702					
143	2	143	13	401/402, 403, 602/LOF, 701/702					
144	11	144	25	401/402, 403, 602/LOF, 701/702					
145	2	145	25	401/402, 403, 602/LOF, 701/702					
146	2	146	3	401/402, 403, 602/LOF, 701/702					
146	6	146	11	401/402, 403, 602/LOF, 701/702					
167	21	167	25						
168	2	168	4						
168	14	168	25						
169	2	169	5						
169	21	169	25	602/LOF					
170	2	170	9	602/LOF					
170	12	170	13						
170	15	170	19	401/402, 403, 602/LOF, 701/702					
170	22	170	25	401/402, 403, 602/LOF, 701/702					
171	3	171	15						
175	25	175	25	401/402, 403, 602/LOF, 701/702					
176	1	176	13	401/402, 403, 602/LOF, 701/702					
178	9	178	25	401/402, 403, 602/LOF, 701/702					
179	2	179	4	401/402, 403, 602/LOF, 701/702					
183	13	183	20	401/402, 403, 701/702					
183	23	183	24	401/402, 403, 701/702					
184	2	184	19	401/402, 403, 701/702					
184	22	184	25	401/402, 403, 701/702					
185	2	185	4	401/402, 403, 701/702					
185	6	185	25	801/802					
186	2	186	25	401/402, 403, 602/LOF, 801/802					

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September 13, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations*	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
187	2	187	8	401/402, 403, 602/LOF, 701/702, 801/802					
187	11	187	17						
187	20	187	25						
188	2	188	4						
188	8	188	20	401/402, 403, 602/LOF, 701/702					
188	23	188	25	401/402, 403, 602/LOF, 701/702					
189	12	189	19	401/402, 403					
191	12	191	25	401/402, 403, 602/LOF					
192	2	192	10	401/402, 403, 602/LOF					
192	15	192	17	401/402, 403, 602/LOF					
192	20	192	25	401/402, 403, 602/LOF					
193	2	193	3	401/402, 403, 602/LOF					
193	18	193	21	401/402, 403, 602/LOF					
196	14	196	25						
197	2	197	25						
198	1	198	5						
198	15	198	23	401/402, 403, 602/LOF					
200	2	200	25	401/402, 403					
201	2	201	25	401/402, 403					
202	2	202	5						
203	4	203	25	401/402, 403, P, AA					
204	2	204	18	401/402, 403, NR, AA					
205	2	205	5	401/402, 403, MC					
205	8	205	12	401/402, 403, MC					
208	5	208	25						
209	2	209	10						
209	13	209	25						
210	2	210	5	401/402, 403					
211	11	211	25	401/402, 403, P, AA					
212	2	212	3	401/402, 403, P, AA					
212	5	212	11	401/402, 403, P, AA					
212	13	212	19	401/402, 403					
238	5	238	15	401/402, 403, 602/LOF					
239	4	239	9	401/402, 403, 602/LOF					
240	7	240	18	401/402, 403, 602/LOF					
241	10	241	20	401/402, 403, 602/LOF					
241	23	241	25						
242	2	242	25						
243	2	243	22	401/402, 403, 602/LOF					

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September 13, 2019

Defendant's Initial Beg Page	Defendant's Initial Beg Line	Defendant's Initial End Page	Defendant's Initial End Line	Plaintiffs' Objections to Defendant's Initial Designations*	Plaintiffs' Counter Beg Page	Plaintiffs' Counter Beg Line	Plaintiffs' Counter End Page	Plaintiffs' Counter End Line	Defendant's Objections to Plaintiffs' Counter Designations
247	4	247	25						
248	2	248	25	401/402, 403, 602/LOF, 701/702					
249	1	249	13	401/402, 403, 602/LOF, 701/702					
249	16	249	25	401/402, 403, 602/LOF, 701/702					
250	2	250	6	401/402, 403, 602/LOF, 701/702					
250	9	250	10	401/402, 403, 602/LOF, 701/702					
250	22	250	25						
251	2	251	21	401/402, 403, 602/LOF					
252	7	252	23	401/402, 403, 602/LOF, 701/702					
254	16	254	22	401/402, 403, 602/LOF					
255	12	255	25	401/402, 403, 602/LOF, 701/702					
256	2	256	5	401/402, 403, 602/LOF, 701/702					
256	8	256	18	401/402, 403					
258	19	258	25	401/402, 403					
260	2	260	25	401/402, 403, 602/LOF, 701/702					
261	2	261	2	401/402, 403, 602/LOF, 701/702					
261	5	261	6	401/402, 403, 602/LOF, 701/702					
261	8	261	14	401/402, 403, 602/LOF, 701/702					
264	5	264	10	401/402, 403, 602/LOF, Legal					
264	13	264	13	401/402, 403, 602/LOF, Legal					
266	11	266	25	401/402, 403, 602/LOF					
267	2	267	7	401/402, 403, 602/LOF, Legal					
267	10	267	11	401/402, 403, 602/LOF, Legal					
267	13	267	25	401/402, 403, 602/LOF, Legal					
268	3	268	13	401/402, 403, 602/LOF, Legal					

*Par objects to all designated testimony for this witness pursuant to Fed. R. Evid. 801, 802, and 804, and Fed. R. Civ. P. 45 as the witness is within the subpoena power of the District of Delaware and Eagle has not demonstrated the witness is unavailable.

Exhibit

Par's Objection Key	
Code	Objection
106	partial document/lacks context (FRE 106)
401/402	lacks relevance (FRE 401/402)
403	unduly prejudicial/confusing/waste of time (FRE 403)
501/502	Privilege/Work Product (FRE 501/502)
602/LOF	lacks foundation/speculative (FRE 602)
701/702	improper opinion (FRE 701/702)
801-802	hearsay (FRE 802)
901/902	lacks authenticity (FRE 901/902)
1002	original document required (FRE 1002)
1003	incomplete/illegible (FRE 1003)
1006	improper summary (FRE 1006)
ID	insufficient/incorrect description
L	late/not produced
AA	attorney argument improperly offered as evidence; contains counsel colloquy or objections
C	compound
Legal	calls for a legal conclusion
Leading	leading question of a non-hostile witness
MC	Mischaracterizes/misstates witness's testimony
NR	nonresponsive
PMIL	Subject of pending motion in limine
P	privilege
OS	beyond the scope
V	Vague and/or ambiguous

GENERAL OBJECTIONS

Eagle's objections are preliminary and based on Eagle's present knowledge and understanding. Eagle reserves the right to amend or supplement its objections at any time and for any reason prior to the filing of the Pretrial Order with the Court and as otherwise appropriate. Eagle reserves the right to assert additional objections to Plaintiffs' counter deposition designations based on case developments and when deposition testimony is offered at trial. Eagle objects to Par's counter designations for failing to identify which designations it contends should be considered to counter Eagle's affirmative deposition designations, if introduced. See Fed. R. Civ. Pro. 32(a)(6). Rather, Par listed its counter designations sequentially, depriving Eagle fair notice of what Par intends to introduce in conjunction with Eagle's affirmative designations.

Eagle's Objection Code	
Code	Objection
R	Fed. R. Evid. 401 and 402. Relevance.
403	Fed. R. Evid. 403. Any relevance substantially outweighed by confusion, prejudice, or waste of time.
AF	Assumes facts not in evidence.
C	Attorney colloquy or objection.
Form	E.g., vague, compound, argumentative, asked and answered, misstates, leading.
F	Fed. R. Evid. 602. Lack of foundation.
H	Fed. R. Evid. 801 & 802. Hearsay
Inc	Incomplete.
Lay	Fed. R. Evid. 701. Lay opinion testimony.
NA	No answer.
NQP	No question posed.
NR	Non-responsive. Witness's answer not responsive to the question asked.
NS	Nonsensical.
S	Speculation
32	Fed. R. Civ. Pro. 32. Improper Counter Designation.

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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

<p>PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC and ENDO PAR INNOVATION COMPANY, LLC,</p> <p>Plaintiffs,</p> <p>v.</p> <p>EAGLE PHARMACEUTICALS INC.,</p> <p>Defendant.</p>	<p>C.A. No. 18-cv-823-CFC</p> <p>[REDACTED]</p>
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BRIEF STATEMENT OF WHAT PLAINTIFFS INTEND TO PROVE

Pursuant to Local Rule 16.3(c)(8), Plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC (collectively “Par” or “Plaintiffs”) submit the following brief statement of the principal matters Plaintiffs intend to prove at trial. This statement is not exhaustive, and Plaintiffs reserve the right to prove any matter identified in its pleadings, discovery responses, expert reports, and the accompanying statement of issues of facts and issues of law that remain to be litigated at trial. Plaintiffs may also provide additional proof to rebut any proof offered by Defendant before and during trial, in response to rulings by the Court, or for other good cause. Plaintiffs reserve the right to modify or amend this Statement to the extent necessary to reflect any

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future rulings by the Court, and to supplement or amend this Statement to fairly respond to any new issues that Defendant may raise. Plaintiffs incorporate by reference their expert reports in support of any proof to be presented by expert testimony.

I. ISSUES ON WHICH PLAINTIFFS BEAR THE BURDEN OF PROOF

A. Infringement

1. Eagle's ANDA No. 211538 ("Eagle's ANDA") seeks FDA approval to make, use and sell Vasopressin Injection, USP, 20 units/1 mL (20 units/mL) (the "Proposed ANDA Product") as a generic version of Par's VASOSTRICT product before expiration of U.S. Patent Nos. 9,687,526 ("the '526 patent"), 9,744,209 ("the '209 patent), and 9,750,785 ("the '785 patent) (collectively the "Patents-in-Suit" or "Asserted Patents").

2. Par timely listed the Asserted Patents in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluation*, commonly referred to as the "Orange Book," pursuant to 21 U.S.C. §§ 355(b)(1) and (c)(2), and 21 C.F.R. § 314.53(e).

3. Eagle's ANDA includes paragraph IV certifications to the Asserted Patents pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), certifying that Eagle believes the Asserted Patents are invalid or will not be infringed by the commercial manufacture, use, or sale of Eagle's Proposed ANDA Product.

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4. Par will prove by a preponderance of the evidence that the submission of Eagle's ANDA to the FDA constitutes infringement of the Asserted Patents pursuant to 35 U.S.C. § 271(e)(2).

5. Par will prove by a preponderance of the evidence that, if Eagle's ANDA were to be approved by the FDA, Eagle's commercial manufacture, use, offer for sale, sale, and/or importation of Eagle's Proposed ANDA Product—with its accompanying package insert—before expiration of the Asserted Patents, would directly or indirectly infringe the Asserted Patents pursuant to 35 U.S.C. § 271(a) and/or (b).

B. Requested Relief

6. Par seeks a judgment that Eagle's ANDA filing is an infringement of the '526 patent, and a declaration that Eagle's commercial manufacture, distribution, use, and sale of its Proposed AND Product would induce infringement of the '526 patent.

7. Par seeks a judgment that Eagle's ANDA filing is an infringement of the '785 patent, and a declaration that Eagle's commercial manufacture, distribution, use, and sale of its Proposed AND Product would infringe and/or induce infringement of the '785 patent.

8. Par seeks a judgment that Eagle's ANDA filing is an infringement of the '209 patent, and a declaration that Eagle's commercial manufacture,

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distribution, use, and sale of its Proposed AND Product would induce infringement of the '209 patent.

9. Par seeks an order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of Eagle's ANDA No. 211538 shall not be earlier than the last expiration date of the Asserted Patents, including any extensions thereof.

10. Par seeks a permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B) and 35 U.S.C. § 283, restraining and enjoining Eagle, its officers, agents, servants and employees, and those persons in active concert or participation with any of them, from infringement of the Asserted Patents for the full terms thereof, including any extensions thereof.

11. Par seeks an order that damages or other monetary relief be awarded to Par if Eagle were to engage in the commercial manufacture, use, offer to sell, sale, distribution or importation of Eagle's Proposed ANDA Products, or induce such conduct by others, prior to the expiration of the Asserted Patents, and any additional period of exclusivity to which Plaintiffs are or become entitled, and that any such damages or monetary relief be trebled and awarded to Par with prejudgment interest.

12. Par seeks reasonable attorneys' fees, filing fees, and reasonable costs of suit incurred by Par in this action.

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13. Par seeks such other and further relief as the Court may deem just and proper.

C. Exceptional Case

14. Par will prove that this is an exceptional case under 35 U.S.C. § 285, and Par should be awarded attorneys' fees.

II. ISSUES ON WHICH DEFENDANT BEARS THE BURDEN OF PROOF

A. Invalidity

15. Eagle bears the burden of proof by clear and convincing evidence on the invalidity of the Asserted Claims of the '526, '209, and '785 patents. Eagle cannot meet that burden with respect to any Asserted Claim.

16. Par will show that Eagle has not met that burden of proof with respect to any of its asserted grounds of invalidity. Par will, to the extent necessary, introduce evidence to rebut each of Eagle's invalidity contentions, which include anticipation, obviousness, lack of written description, lack of enablement, and indefiniteness.

17. Par will show that Eagle has failed to demonstrate by clear and convincing evidence that any Asserted Claim is invalid as anticipated.

18. Par will show that Eagle has failed to demonstrate by clear and convincing evidence that Original VASOSTRICT anticipates any of the Asserted Claims.

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19. Par will show that Eagle has failed to demonstrate that any Original VASOSTRICT product that was on sale or in public use before the filing dates of the Asserted Claims satisfied every limitation of any Asserted Claim.

20. Par will show that Eagle has failed to demonstrate by clear and convincing evidence that PITRESSIN anticipates any of the asserted '785 claims.

21. Par will show that Eagle has failed to demonstrate that any PITRESSIN product that was on sale or in public use before the filing dates of the Asserted Claims satisfied every limitation of any asserted '785 claim.

22. Par will show that Eagle has failed to demonstrate by clear and convincing evidence that any Asserted Claim is invalid as obvious.

23. Par will show that Eagle has failed to demonstrate by clear and convincing evidence that any of the Asserted Claims are obvious in view of any of the following grounds:

Patent	Claim(s)	Grounds
'526 patent	Claim 13	1) Obviousness over Original VASOSTRICT with its prescribing information 2) Obviousness over PITRESSIN with its prescribing information in view of WHO Standard, Russell 2008, and Intravenous Medications 2013 3) Obviousness over PPC in view of WHO Standard, Russell 2008, and Intravenous Medications 2013 4) Obviousness over the April 2014 VASOSTRICT Label

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Patent	Claim(s)	Grounds
		5) Obviousness over American Regent Vasopressin Injection with its prescribing information in view of Russell 2008 and Intravenous Medications 2013
'209 patent	Claims 1, 3, 4, 5, 7	1) Obviousness over Original VASOSTRICT with its prescribing information 2) Obviousness over PITRESSIN with its prescribing information in view of Russell 2008 and Intravenous Medications 2013 3) Obviousness over PPC in view of Russell 2008 and Intravenous Medications 2013 4) Obviousness over the April 2014 VASOSTRICT Label 5) Obviousness over American Regent Vasopressin Injection with its prescribing information in view of Russell 2008 and Intravenous Medications 2013
'785 Patent	Claims 1, 4, 5, 8	1) Obviousness over Original VASOSTRICT with its prescribing information 2) Obviousness over PITRESSIN with its prescribing information 3) Obviousness over PPC 4) Obviousness over the April 2014 VASOSTRICT Label 5) Obviousness over American Regent Vasopressin Injection with its prescribing information

24. Par will show that Eagle has failed to demonstrate that any prior art in combination with other prior art and/or in view of the knowledge of a person of ordinary skill in the art (“POSA”) would have rendered obvious the claimed inventions of the Asserted Patents. Par will show the significant differences between the prior art and the claimed inventions. Par will also show that Eagle has

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failed to demonstrate any motivation for a POSA to have thought of either combining two or more references or modifying one reference to achieve the claimed inventions in the manner that Eagle proposes. Additionally, Par will show that Eagle has failed to demonstrate that a POSA would have had a reasonable expectation of success in making the claimed inventions.

25. Par will show that Eagle has failed to demonstrate by clear and convincing evidence that any Asserted Claim is invalid for lack of adequate written description.

26. Par will show that Eagle has failed to demonstrate that there is not adequate written description support in the specification of the '526 patent for a composition that is stored at 2-8°C for at least four weeks and that exhibits “less than 1% degradation after storage at 2-8° C. for about four weeks.”

27. Par will show that Eagle has failed to demonstrate that there is not adequate written description support in the specifications of the Asserted Patents for the full scope of the claimed compositions.

28. Par will show that Eagle has failed to demonstrate that there is not adequate written description support in the specification of the '209 and '785 patents for a composition with “0.1%” SEQ ID NO.: 3.

29. Par will show that Eagle has failed to demonstrate by clear and convincing evidence that any Asserted Claim is invalid for lack of enablement.

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30. Par will show that Eagle has failed to demonstrate that there is not adequate enablement support in the specifications of the Asserted Patents for the full scope of the claimed compositions.

31. Par will show that Eagle has failed to demonstrate by clear and convincing evidence that any Asserted Claim is invalid as indefinite.

32. Par will show that Eagle has failed to demonstrate that the asserted '526 claim, read in light of the specification of the '526 patent and the prosecution history, does not inform a POSA with reasonable certainty about the scope of “less than [X]% degradation after storage at 2-8° C. for about four weeks.”

33. Par will show that Eagle has failed to demonstrate that the Asserted Claims, read in light of the specifications and the prosecution histories, do not inform a POSA with reasonable certainty about when to measure pH.

34. Thus, with respect to each of Eagle's invalidity allegations, Par will show that Eagle has failed to satisfy its burden of proving invalidity by clear and convincing evidence.

B. Enforceability

35. Eagle has failed to prove by clear and convincing evidence that any Asserted Claim of the Patents in Suit is unenforceable.

36. Par will demonstrate that Eagle has not met its burden in proving that Vinayagam Kannan, Craig Kenesky, and/or Michelle Bonomi-Huvala committed

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inequitable conduct during the prosecution of U.S. Patent No. 9,744,239 (the “’239 patent”).

37. Par will demonstrate that Eagle has not met its burden in proving that Vinayagam Kannan, Craig Kenesky, and/or Michelle Bonomi-Huvala committed affirmative egregious misconduct through submission of declarations to the U.S. Patent & Trademark Office (“PTO”) during the prosecution of the ’239 patent.

38. Par will demonstrate that Eagle has not met its burden in proving that the Kannan and Bonomi-Huvala declarations are material to patentability.

39. Par will demonstrate that Eagle has not met its burden in proving that the Kannan and Bonomi-Huvala declarations were submitted with specific intent to deceive the PTO.

40. Par will demonstrate that Eagle has not met its burden in proving that Vinayagam Kannan, Craig Kenesky, and/or Michelle Bonomi-Huvala acted with the specific intent to mislead or deceive the PTO.

41. Par will demonstrate that Eagle has not met its burden in proving that the Asserted Patents are unenforceable under the doctrine of infectious unenforceability.

42. Par will demonstrate that Eagle has not met its burden in proving that the Asserted Patents are unenforceable as a result of alleged non-disclosure of the properties of the prior art PITRESSIN product.

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43. Par will demonstrate that Eagle has not met its burden in proving that the information allegedly not disclosed to the PTO by the named inventors regarding the prior art PITRESSIN product was material to the patentability of the Asserted Patents.

44. Par will demonstrate that Eagle has not met its burden in proving that the named inventors failed to disclose the prior art PITRESSIN product with specific intent to deceive the PTO.

45. Par will demonstrate that Eagle has not met its burden in proving that the Asserted Patents are unenforceable based on the alleged withholding or misrepresenting of information relating to the criticality of the pH limitations recited in the Asserted Claims.

46. Par will demonstrate that Eagle has not met its burden in proving that the Asserted Patents are unenforceable based on [REDACTED]
[REDACTED]
that any such alleged non-disclosure was but-for material to the patentability of the Asserted Patents, or that any such alleged non-disclosure was conducted with the specific intent to deceive the PTO.

47. Par will demonstrate that Eagle has not met its burden in proving that the named inventors failed to disclose [REDACTED]
[REDACTED] that such alleged non-disclosure

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was but-for material to the patentability of the Asserted Patents, or that such alleged non-disclosure was conducted with the specific intent to deceive the PTO.

C. Exceptional Case


48. Par will demonstrate that Eagle has not met its burden in proving that this is an exceptional case under 35 U.S.C. § 285, such that Defendants should not be awarded attorneys' fees.

D. Other Affirmative Defenses and Counterclaims

49. Par will, to the extent necessary, introduce evidence to rebut any other affirmative defenses and counterclaims presented by Eagle.

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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

PAR PHARMACEUTICAL, INC.,)	
PAR STERILE PRODUCTS, LLC, and)	
ENDO PAR INNOVATION)	
COMPANY, LLC,)	
)	C.A. No. 18-823-CFC
Plaintiffs,)	
)	
v.)	
)	
EAGLE PHARMACEUTICALS INC.,)	
)	
Defendant.)	

DEFENDANT'S STATEMENT OF INTENDED PROOF

Pursuant to Local Rule 16.3(c)(9), Defendant Eagle Pharmaceuticals Inc. (“Eagle”) respectfully submits the following brief statement of what it intends to prove at trial. Eagle may prove the matters set forth in its pleadings, contentions, written discovery responses, experts’ reports, and experts’ depositions. In addition, in support of such proofs, Eagle may provide background testimony in connection with such proofs. Eagle also intends to offer proof on the issues of fact and law identified in this Pretrial Order as well as proof to rebut items on which Plaintiffs Par Pharmaceuticals, Inc., Par Sterile Product, LLC., and Endo Par Innovation Co., LLC (collectively, “Plaintiffs”) offer proof.

In this action, Plaintiffs are currently asserting U.S. Patent No. 9,687,526 (“the ’526 patent”); U.S. Patent No. 9,744,209 (“the ’209 patent”); and U.S. Patent No. 9,750,785 (“the ’785 patent”) (collectively, the “Patents-in-Suit”).¹ Specifically, Plaintiffs are asserting claim 13 of the ’526 patent; claims 1, 3–5, and 7 of the ’209 patent; and claims 1, 4, 5, and 8 of the ’785 patent (the “Asserted Claims”).

Eagle’s following statement is based, in relevant part, on its current understanding of Plaintiffs’ positions and the prior proceedings in this litigation.

¹ The Patents-in-Suit share two common inventors and a common chain of priority to U.S. Patent No. 9,744,239 (“the ’239 patent”), and therefore may be referred to as the “’239 family.” Each of these patents also claims priority to U.S. Application 14/610,499. Par has not disputed that the Patents-in-Suit are not entitled to priority dates earlier than their own filing dates, based on their claims of priority to the ’239 patent and ’499 application.

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Eagle reserves the right to amend or supplement this statement to fairly respond to any new positions or evidence Plaintiffs raise or any future ruling of this Court. Eagle expressly reserves the right to amend or supplement this statement in response to Plaintiffs' Pretrial Order submissions, pretrial proceedings, trial proceedings, or post-trial briefing.

To the extent Eagle asserts that Plaintiffs have failed to meet their burden of proof on any issue, such statement does not constitute an admission that Eagle has any obligation to prove or disprove any element or any part of any claim or defense on which Plaintiffs bear the burden of proof or production. Eagle does not assume the burden of proof or production as to any matter set forth below unless required to do so by law.

In addition to the below statement, Eagle incorporates by reference its experts' reports regarding those matters to be proved by or in part by expert testimony.

I. NONINFRINGEMENT

1. Eagle will show that Plaintiffs cannot satisfy their burden of proving by a preponderance of the evidence that any of the Asserted Claims of the Patents-in-Suit claims the drug, or use of the drug, that is the subject of Eagle's ANDA No. 211538 such that the submission of that ANDA constituted infringement of any of the Asserted Claims of the Patents-in-Suit pursuant to 35 U.S.C. § 271(e)(2).

2. Eagle will show that Plaintiffs cannot satisfy their burden of proving by a preponderance of the evidence that, if Eagle's ANDA No. 211538 were to be approved by the FDA, the manufacture, use, offer for sale, sale, or importation of the drug that is the subject of that ANDA would constitute direct infringement of any of the Asserted Claims of the Patents-in-Suit by Eagle.

3. Eagle will show that Plaintiffs cannot satisfy their burden of proving by a preponderance of the evidence that, if Eagle's ANDA No. 211538 were to be approved by the FDA, the manufacture, use, offer for sale, sale, or importation of the drug that is the subject of that ANDA would constitute direct infringement of any of the Asserted Claims of the Patents-in-Suit by any third parties.

4. Eagle will show that, to the extent Plaintiffs prove direct infringement of the Asserted Claims by a third party (rather than by Eagle), Plaintiffs cannot satisfy their burden of proving by a preponderance of the evidence that, if Eagle's ANDA No. 211538 were to be approved by the FDA, the manufacture, use, sale,

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offer for sale, or importation of the drug that is the subject of that ANDA will actively induce infringement of any of the Asserted Claims of the Patents-in-Suit.

A. '526 Patent

5. Eagle will show that Plaintiffs cannot satisfy their burden of proving by a preponderance of the evidence that the drug that is the subject of ANDA No. 211538 will, if approved, literally meet the composition limitations of claim 13 of the '526 patent.

6. Eagle will show that Plaintiffs cannot satisfy their burden of proving by a preponderance of the evidence that the use of the drug that is the subject of ANDA No. 211538 will, if approved, literally infringe claim 13 of the '526 patent.

7. Eagle will show that Plaintiffs cannot satisfy their burden of proving by a preponderance of the evidence that Eagle will induce others to literally infringe claim 13 of the '526 patent using the drug that is the subject of ANDA No. 211538, if approved.

8. Eagle will show that Plaintiffs cannot satisfy their burden of proving by a preponderance of the evidence that Eagle has the specific intent to induce others to literally infringe claim 13 of the '526 patent using the drug that is the subject of ANDA No. 211538, if approved.

9. Eagle will show that Plaintiffs cannot satisfy their burden of proving by a preponderance of the evidence that a single individual will literally infringe claim

13 of the '526 patent using the drug that is the subject of ANDA No. 211538, if approved.

B. '209 Patent

10. Eagle will show that Plaintiffs cannot satisfy their burden of proving by a preponderance of the evidence that the drug that is the subject of ANDA No. 211538 will, if approved, literally meet the composition limitations of claims 1, 3, 4, 5, and 7 of the '209 patent.

11. Eagle will show that Plaintiffs cannot satisfy their burden of proving by a preponderance of the evidence that the use of the drug that is the subject of ANDA No. 211538 will, if approved, literally infringe claims 1, 3, 4, 5, and 7 of the '209 patent.

12. Eagle will show that Plaintiffs cannot satisfy their burden of proving by a preponderance of the evidence that Eagle will induce others to literally infringe claims 1, 3, 4, 5, and 7 of the '209 patent using the drug that is the subject of ANDA No. 211538, if approved.

13. Eagle will show that Plaintiffs cannot satisfy their burden of proving by a preponderance of the evidence that Eagle has the specific intent to induce others to literally infringe claims 1, 3, 4, 5, and 7 of the '209 patent using the drug that is the subject of ANDA No. 211538, if approved.

C. '785 Patent

14. Eagle will show that Plaintiffs cannot satisfy their burden of proving by a preponderance of the evidence that the drug that is the subject of ANDA No. 211538 will, if approved, literally infringe claims 1, 4, 5, and 8 of the '785 patent.

15. Eagle will show that Plaintiffs cannot satisfy their burden of proving by a preponderance of the evidence that Eagle will directly infringe claims 1, 4, 5, and 8 of the '785 patent.

16. Eagle will show that Plaintiffs cannot satisfy their burden of proving by a preponderance of the evidence that Eagle will induce others to literally infringe claims 1, 4, 5, and 8 of the '785 patent.

17. Eagle will show that Plaintiffs cannot satisfy their burden of proving by a preponderance of the evidence that Eagle has the specific intent to induce others to literally infringe claims 1, 4, 5, and 8 of the '785 patent.

II. INEQUITABLE CONDUCT

18. Eagle will prove that Vinayagam Kannan, Craig Kenesky, and Michelle Bonomi-Huvala committed inequitable conduct during the prosecution of U.S. Patent No. 9,744,239 (the "'239 patent), which renders that patent unenforceable.

19. Eagle will prove that Vinayagam Kannan, Craig Kenesky, and Michelle Bonomi-Huvala committed affirmative egregious misconduct through submission

of false declarations to the U.S. Patent & Trademark Office (“PTO”) during the prosecution of the ’239 patent.

20. Specifically, facing an anticipation and obviousness rejection by the Examiner over the prior art April 2014 Vasostrict® Label, the declarations falsely represented to the Examiner that the named inventors of the ’239 patent—Vinayagam Kannan and Matthew Kenney—invented the subject matter set forth in the April 2014 Vasostrict® Label relied on by the Examiner, and that the named inventors had provided that subject matter to Par’s Regulatory Group for submission to the FDA.

21. Based on the false representations, Par’s prosecution counsel Craig Kenesky asked the Examiner to remove the April 2014 Vasostrict® Label from her consideration as prior art pursuant to Title 35, Section 102(b)(1)(A) of the America Invents Act.

22. Eagle will prove that the named inventors did not in fact invent the subject matter set forth in the April 2014 Vasostrict® Label, and that the declarants and Mr. Kenesky knew that the named inventors did not in fact invent the subject matter set forth in the April 2014 Vasostrict® Label.

23. Eagle will prove that the Examiner accepted the false representations set forth in the Kannan and Bonomi-Huvala declarations, and as a result thereof, the Examiner proceeded to remove the April 2014 Vasostrict® Label from her

consideration as prior art and withdrew her anticipation and obviousness rejections based on that reference.

24. Par no longer disputes that the April 2014 Vasostrict® Label is prior art to the '239 patent or the Patents-in-Suit. Par has voluntarily dismissed the '239 patent from this action.

25. The unmistakably false Kannan and Bonomi-Huvala declarations are presumed to be material and submitted with intent to deceive. However, to the extent necessary, Eagle will prove that the submission of the false declarations during the prosecution of the '239 patent, and the Examiner's subsequent withdrawal of her anticipation rejection based on the April 2014 Vasostrict® Label, were material to the patentability of the patent.

26. Further, to the extent necessary, Eagle will prove that Vinayagam Kannan, Craig Kenesky, and Michelle Bonomi-Huvala submitted the false declarations with the specific intent to mislead or deceive the PTO.

27. Eagle will prove that the Patents-in-Suit, which are continuations-in-part of the '239 patent, are also unenforceable due to the inequitable conduct committed during the prosecution of the '239 patent, under the doctrine of infectious unenforceability.

28. Eagle will prove that the Patents-in-Suit are also unenforceable because the named inventors committed inequitable conduct by withholding information regarding the prior art Pitressin® product from the PTO.

29. Eagle will prove that the information withheld from the PTO by the named inventors regarding the prior art Pitressin® product was material to the patentability of the Patents-in-Suit.

30. Eagle will prove that the named inventors withheld the information regarding the prior art Pitressin® product from the PTO with specific intent to mislead or deceive the PTO.

31. Eagle will prove that the Patents-in-Suit are further unenforceable because the named inventors committed inequitable conduct by intentionally withholding and misrepresenting information relevant to their assertions of criticality of the pH limitations set forth in the claims of the '239 patent and the Patents-in-Suit.

32. Specifically, the named inventors only secured the issuance of the '239 patent and the Patents-in-Suit by submitting a series of declarations during prosecution alleging that three distinct pH values and ranges (i.e., 3.5–4.1, 3.7–3.9, and 3.8) are critical to stability of vasopressin formulations, and therefore are nonobvious.

33. Eagle will prove that the named inventors withheld material information from the PTO that relates to their allegations of criticality, including an undisclosed pH-stability study based on which the named inventors internally concluded that pH 3.5, not the claimed pH of 3.7–3.9 or 3.8, is optimal for vasopressin.

34. Eagle will also prove that the named inventors withheld information that disproves and undermines their allegations of criticality of the claimed pH values, including normalized impurity data and the degree of variability present in the data they submitted to the Examiner.

35. Eagle will prove that the information that the inventors withheld relating to the alleged criticality of the claimed pH values was material to the patentability of the Patents-in-Suit.

36. Eagle will prove that the named inventors withheld the information relating to the alleged criticality of the claimed pH values from the PTO with specific intent to mislead or deceive the PTO.

III. INVALIDITY

A. '526 Patent

37. Eagle will prove by clear and convincing evidence that claim 13 of the '526 patent is invalid as anticipated.

38. Eagle will prove by clear and convincing evidence that claim 13 of the '526 patent is invalid because the claimed invention would have been obvious to a person of ordinary skill in the art ("POSA") as of the effective filing date of that claim, in light of the scope and content of the prior art, the differences between the claim and the prior art, and the level of ordinary skill in the art at the time.

39. Specifically, Eagle will prove by clear and convincing evidence that claim 13 of the '526 patent is invalid as obvious in light of various combinations of prior art references and/or the knowledge and skill in the art as of the effective filing date of that claim. Eagle will prove by clear and convincing evidence that the combinations of these prior art references disclose every limitation of claim 13 of the '526 patent, that a POSA would have had a reason or motivation to combine the teachings of the references to obtain the subject matter of that claim, and that a POSA would have had a reasonable expectation of success.

40. Eagle will prove that claim 13 of the '526 patent is invalid as anticipated by the prior sale and public use of Original Vasostrict®² with its prescribing information.

² "Original Vasostrict®," as used herein, refers to Par's original Vasostrict® product as approved by the U.S. Food & Drug Administration ("FDA") in April 2014.

41. Eagle will prove that claim 13 of the '526 patent is invalid as obvious over the prior sale and public use of Original Vasopressin® with its prescribing information, in light of the full scope and content of the prior art and the level of ordinary skill in the art at the time.

42. Eagle will prove that claim 13 of the '526 patent is invalid as obvious over the April 2014 Vasopressin® Label, in light of the full scope and content of the prior art and the level of ordinary skill in the art at the time.

43. Eagle will prove that claim 13 of the '526 patent is invalid as obvious over the prior sale and public use of Pitressin® with its prescribing information in view of Intravenous Medications 2013,³ Russell 2008,⁴ and WHO Standard,⁵ in light of the full scope and content of the prior art and the level of ordinary skill in the art at the time.

44. Eagle will prove that claim 13 of the '526 patent is invalid as obvious over the prior sale and public use of American Regent Vasopressin Injection with its prescribing information in view of Intravenous Medications 2013 and Russell 2008,

³ Intravenous Medications (B. L. Gahart & A. R. Nazerano et al., eds. 29th ed. 2013) ("Intravenous Medications 2013").

⁴ J. A. Russell et al., *Vasopressin versus Norepinephrine Infusion in Patients with Septic Shock*, N. Eng. J. Med. 358(9):877-87 (2008) ("Russell 2008").

⁵ *WHO International Standard: Arginine Vasopressin (AVP)*, Nat'l. Inst. for Biol. Standards & Control (Apr. 30, 2013) ("WHO Standard").

in light of the full scope and content of the prior art and the level of ordinary skill in the art at the time.

45. Eagle will prove that claim 13 of the '526 patent is invalid as obvious over PPC⁶ in view of Intravenous Medications 2013, Russell 2008, and WHO Standard, in light of the full scope and content of the prior art and the level of ordinary skill in the art at the time.

46. The specific obviousness combinations listed above do not include the background references Eagle may rely on for establishing the state of the art, motivation, or expectation of success. Eagle may rely on additional references to establish the state of the art, motivation, or expectation of success. Eagle may also rely on additional references to rebut non-obviousness arguments raised by Plaintiffs.

47. Eagle will prove by clear and convincing evidence that claim 13 of the '526 patent is invalid for lack of adequate written description.

48. Eagle will prove that claim 13 of the '526 patent is invalid for lack of adequate written description of a composition that is stored at 2–8°C for at least four weeks and exhibits “less than 1% degradation after storage at 2-8 °C. for about four weeks.”

⁶ Pharm. Partners Can., *Vasopressin Injection*, USP (June 2009) (“PPC”).

49. Eagle will prove that claim 13 of the '526 patent is invalid for lack of adequate written description of the full scope of the claimed compositions.

50. Eagle will prove by clear and convincing evidence that claim 13 of the '526 patent is invalid for lack of enablement.

51. Eagle will prove that claim 13 of the '526 patent is invalid for lacking enablement of the full scope of the claimed compositions.

52. Eagle will prove by clear and convincing evidence that claim 13 of the '526 patent is invalid as indefinite.

53. Eagle will prove that claim 13 of the '526 patent is invalid as indefinite because a person of ordinary skill in the art would not be able to determine with reasonable certainty the scope of "less than 5% [1%] degradation after storage at 2-8 °C. for about four weeks."

54. Eagle will prove that claim 13 of the '526 patent is invalid as indefinite because a person of ordinary skill in the art would not be able to determine with reasonable certainty when to measure pH.

B. '209 Patent

55. Eagle will prove by clear and convincing evidence that claims 1, 3, 4, 5, and 7 of the '209 patent are invalid as anticipated.

56. Eagle will prove by clear and convincing evidence that claims 1, 3, 4, 5, and 7 of the '209 patent are invalid because the claimed inventions would have

been obvious to a POSA as of the effective filing date of that claim, in light of the scope and content of the prior art, the differences between the claim and the prior art, and the level of ordinary skill in the art at the time.

57. Specifically, Eagle will prove by clear and convincing evidence that claims 1, 3, 4, 5, and 7 of the '209 patent are invalid as obvious in light of various combinations of prior art references and/or the knowledge and skill in the art as of the effective filing date of that claim. Eagle will prove by clear and convincing evidence that the combinations of these prior art references disclose every limitation of claims 1, 3, 4, 5, and 7 of the '209 patent, that a POSA would have had a reasonable motivation to combine the teachings of the references to obtain the subject matter of those claims, and that a POSA would have had a reasonable expectation of success.

58. Eagle will prove that claims 1, 3, 4, 5, and 7 of the '209 patent are invalid as anticipated by the prior sale and public use of Original Vasostrict® with its prescribing information, in light of the full scope and content of the prior art and the level of ordinary skill in the art at the time.

59. Eagle will prove that claims 1, 3, 4, 5, and 7 of the '209 patent are invalid as obvious over the prior sale and public use of Original Vasostrict® with its prescribing information, in light of the full scope and content of the prior art and the level of ordinary skill in the art at the time.

60. Eagle will prove that claims 1, 3, 4, 5, and 7 of the '209 patent are invalid as obvious over the April 2014 Vasostrict® Label, in light of the full scope and content of the prior art and the level of ordinary skill in the art at the time.

61. Eagle will prove that claims 1, 3, 4, 5, and 7 of the '209 patent are invalid as obvious over the prior sale and public use of Pitressin® with its prescribing information in view of Intravenous Medications 2013 and Russell 2008, in light of the full scope and content of the prior art and the level of ordinary skill in the art at the time.

62. Eagle will prove that claims 1, 3, 4, 5, and 7 of the '209 patent are invalid as obvious over the prior sale and public use of American Regent Vasopressin Injection with its prescribing information in view of Intravenous Medications 2013 and Russell 2008, in light of the full scope and content of the prior art and the level of ordinary skill in the art at the time.

63. Eagle will prove that claims 1, 3, 4, 5, and 7 of the '209 patent are invalid as obvious over PPC in view of Intravenous Medications 2013 and Russell 2008, in light of the full scope and content of the prior art and the level of ordinary skill in the art at the time

64. The specific obviousness combinations listed above do not include the background references Eagle may rely on for establishing the state of the art, motivation, or expectation of success. Eagle may rely on additional references to

establish the state of the art, motivation, or expectation of success. Eagle may also rely on additional references to rebut non-obviousness arguments raised by Plaintiffs.

65. Eagle will prove by clear and convincing evidence that claims 1, 3, 4, 5, and 7 of the '209 patent are invalid for lack of adequate written description.

66. Eagle will prove that claims 1, 3, 4, 5, and 7 of the '209 patent are invalid for lack of adequate written description of the full scope of the claimed compositions.

67. Eagle will prove that claim 3 of the '209 patent is invalid for lack of adequate written description of a composition with "0.1%" of SEQ. ID. NO. 3.

68. Eagle will prove by clear and convincing evidence that claims 1, 3, 4, 5, and 7 of the '209 patent are invalid for lack of enablement.

69. Eagle will prove that claims 1, 3, 4, 5, and 7 of the '209 patent are invalid for lacking enablement of the full scope of the claimed compositions.

70. Eagle will prove by clear and convincing evidence that claims 1, 3, 4, 5, and 7 of the '209 patent are invalid as indefinite.

71. Eagle will prove that claims 1, 3, 4, 5, and 7 of the '209 patent are invalid as indefinite because a person of ordinary skill in the art would not be able to determine with reasonable certainty when to measure pH.

C. '785 Patent

72. Eagle will prove by clear and convincing evidence that claims 1, 4, 5, and 8 of the '785 patent are invalid as anticipated.

73. Eagle will prove by clear and convincing evidence that claims 1, 4, 5, and 8 of the '785 patent are invalid because the claimed inventions would have been obvious to a POSA as of the effective filing date of that claim, in light of the scope and content of the prior art, the differences between the claim and the prior art, and the level of ordinary skill in the art at the time.

74. Specifically, Eagle will prove by clear and convincing evidence that claims 1, 4, 5, and 8 of the '785 patent are invalid as obvious in light of various combinations of prior art references and/or the knowledge and skill in the art as of the effective filing date of that claim. Eagle will prove by clear and convincing evidence that the combinations of these prior art references disclose every limitation of claims 1, 4, 5, and 8 of the '785 patent, that a POSA would have had a reasonable motivation to combine the teachings of the references to obtain the subject matter of those claims, and that a POSA would have had a reasonable expectation of success.

75. Eagle will prove that claims 1, 4, 5, and 8 of the '785 patent are invalid as anticipated by the prior sale and public use of Original Vasostrict® with its prescribing information.

76. Eagle will prove that claims 1, 4, 5, and 8 of the '785 patent are invalid as obvious over the prior sale and public use of Original Vasostrict® with its prescribing information, in light of the full scope and content of the prior art and the level of ordinary skill in the art at the time.

77. Eagle will prove that claims 1, 4, 5, and 8 of the '785 patent are invalid as obvious over the April 2014 Vasostrict® Label, in light of the full scope and content of the prior art and the level of ordinary skill in the art at the time.

78. Eagle will prove that claims 1, 4, 5, and 8 of the '785 patent are invalid as anticipated by the prior sale and public use of Pitressin® with its prescribing information, in light of the full scope and content of the prior art and the level of ordinary skill in the art at the time.

79. Eagle will prove that claims 1, 4, 5, and 8 of the '785 patent are invalid as obvious over the prior sale and public use of Pitressin® with its prescribing information, in light of the full scope and content of the prior art and the level of ordinary skill in the art at the time.

80. Eagle will prove that claims 1, 4, 5, and 8 of the '785 patent are invalid as obvious over the prior sale and public use of American Regent Vasopressin Injection with its prescribing information, in light of the full scope and content of the prior art and the level of ordinary skill in the art at the time.

81. Eagle will prove that claims 1, 4, 5, and 8 of the '785 patent are invalid as obvious over PPC, in light of the full scope and content of the prior art and the level of ordinary skill in the art at the time.

82. The specific obviousness combinations listed above do not include the background references Eagle may rely on for establishing the state of the art, motivation, or expectation of success. Eagle may rely on additional references to establish the state of the art, motivation, or expectation of success. Eagle may also rely on additional references to rebut non-obviousness arguments raised by Plaintiffs.

83. Eagle will prove by clear and convincing evidence that claims 1, 4, 5, and 8 of the '785 patent are invalid for lack of adequate written description.

84. Eagle will prove that claims 1, 4, 5, and 8 of the '785 patent are invalid for lack of adequate written description of the full scope of the claimed compositions.

85. Eagle will prove that claim 4 of the '785 patent is invalid for lack of adequate written description of a composition with "0.1%" of SEQ. ID. NO. 3.

86. Eagle will prove by clear and convincing evidence that claims 1, 4, 5, and 8 of the '785 patent are invalid for lack of enablement.

87. Eagle will prove that claims 1, 4, 5, and 8 of the '785 patent are invalid for lacking enablement of the full scope of the claimed compositions.

88. Eagle will prove by clear and convincing evidence that claims 1, 4, 5, and 8 of the '785 patent are invalid as indefinite.

89. Eagle will prove that claims 1, 4, 5, and 8 of the '785 patent are invalid as indefinite because a person of ordinary skill in the art would not be able to determine with reasonable certainty when to measure pH.

IV. REMEDIES

90. Eagle will show that it is entitled to judgment that it has not infringed any of the Patents-in-Suit and that the Asserted Claims are invalid and unenforceable.

91. Eagle will show that Plaintiffs are not entitled to judgment against Eagle for infringement of any Asserted Claim. Eagle may introduce evidence to rebut any assertion by Plaintiffs that they are entitled to judgment against Eagle for infringement of any Asserted Claim.

92. Eagle will show that Plaintiffs are not entitled to injunctive relief and cannot satisfy their burden for obtaining an injunction. Eagle may introduce evidence to rebut any assertion by Plaintiffs that they are entitled to injunctive relief.

93. Eagle will show that Plaintiffs are not entitled to damages or other monetary relief. Eagle may introduce evidence to rebut any assertion by Plaintiffs that they are asserted to damages or other monetary relief.

EXHIBIT 14

94. Eagle will show that this case is exceptional under 35 U.S.C. § 285 and the Court should award reasonable attorney fees to Eagle.

95. Eagle will show that the Court should award costs to Eagle.

96. Eagle will show that Plaintiffs are not entitled to costs or attorney fees.

CONFIDENTIAL

EXHIBIT 15.1

PAR'S MOTION *IN LIMINE* NO. 1

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**


<p>PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC and ENDO PAR INNOVATION COMPANY, LLC,</p> <p>Plaintiffs,</p> <p>v.</p> <p>EAGLE PHARMACEUTICALS INC.,</p> <p>Defendant.</p>	<p>C.A. No. 18-cv-823-CFC</p> <p></p>
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EXHIBIT 15.1.1

**PLAINTIFFS' MOTION IN LIMINE #1 TO STRIKE AND PRECLUDE
ANY OPINION AND TESTIMONY REGARDING MATTER NEWLY
RAISED IN DR. PARK'S REPLY EXPERT REPORT**

Eagle’s expert Dr. Kinam Park improperly waited until the final round of expert reports to disclose new prior art and opinions about issues on which Eagle bears the burden of proof. Eagle and Dr. Park could and should have timely disclosed that matter earlier, and their failure to do so has prejudiced Par. Accordingly, the Court should preclude Dr. Park from offering any opinion or testimony regarding the new matter at trial. *See, e.g.*, Fed. R. Civ. P. 37(c)(1); *Intellectual Ventures I LLC v. AT&T Mobility LLC*, No. 12-193, 2017 WL 478565, at *3-4 (D. Del. Jan. 31, 2017) (striking reply report where evidence “was available to [expert witness] at the time he served his opening report”).

Courts apply the *Pennypack* factors in determining whether to exclude evidence under Rule 37(c)(1):

(1) The prejudice or surprise arising from untimely evidence; (2) the ability to cure the prejudice; (3) the extent to which allowing the violation of the scheduling order would disrupt the trial process; and (4) the proponent’s bad faith or willfulness in failing to comply with the court’s order.

Praxair, Inc. v. ATMI, Inc., 445 F. Supp. 2d 460, 469 (D. Del. 2006), *rev’d on other grounds*, 543 F.3d 1306 (Fed. Cir. 2008).

In his reply expert report, Dr. Park raised for the first time Lithuanian Patent No. 4487 (“LT-4487”) as alleged prior art, asserting for example that LT-4487’s pH disclosure “encompass[es] the claimed pH values[.]” Ex. A (Park Reply Report excerpts) ¶ 26. That belated disclosure warrants exclusion under

Pennypack. See, e.g., *Praxair, Inc. v. ATMI, Inc.*, No. 03-1158, 2005 WL 3159054, at *4 (D. Del. Nov. 28, 2005) (excluding prior art references disclosed after fact discovery). Eagle did not cite LT-4487 in its invalidity contentions or its Section 282 disclosures—which listed more than 500 references—or in any opening expert report. Eagle may try to downplay the import of LT-4487 as not a “primary” obviousness reference, but any such argument would be unavailing. The novelty of the claimed pH values is a central point of dispute in this case, and Eagle clearly intends to use Dr. Park’s assertion that LT-4487 allegedly teaches those values as a back-door obviousness argument. Indeed, when Par identified references newly raised in Dr. Park’s opening expert report, Eagle withdrew them. See Ex. B (Email from Eagle’s counsel). Eagle’s refusal to withdraw the newly-raised LT-4487 reference as well underscores its significance in Eagle’s eyes.

Dr. Park also improperly raised in reply new opinions about declarations filed by inventor Vinayagam Kannan and former Par employee Michelle Bonomi-Huvala during prosecution of a patent that is no longer being asserted here. See Ex. A ¶¶ 152, 153, 155. In particular, he opined that those declarations allegedly were false, material to patentability, and impacted the prosecution of the patents that Par actually does assert in this case—all issues on which Eagle bears the burden of proof and therefore should have been included, if at all, in Dr. Park’s

opening expert report. *See id.* Yet, Dr. Park provided no opinions about those declarations in his opening report. Indeed, he never mentioned them.

Dr. Park's untimely disclosures are neither substantially justified nor harmless. There was no excuse for waiting until reply expert reports to raise the above new matter. Par produced LT-4487 to Eagle more than three months before Eagle's final invalidity contentions were served and fact discovery closed, and Eagle alleged inequitable conduct based on the Kannan and Bonomi-Huvala declarations during fact discovery and weeks before the deadline for opening expert reports. Moreover, these belated disclosures prejudiced Par's rebuttal case. Dr. Park's reliance on LT-4487 raises new fact issues—the public accessibility of Lithuanian patents, whether the English translation of LT-4487 is true and accurate, and the significance and extent of differences between the naturally-derived vasopressin disclosed in LT-4487 and the synthetic vasopressin claimed in the patents-in-suit. Eagle's untimely disclosures deprived Par of appropriate fact discovery on these issues and Par's expert of rebutting Dr. Park's new opinions, and that prejudice cannot be cured before trial.

Accordingly, the Court should strike paragraphs 26, 152, 153, and 155 of Dr. Park's reply expert report and preclude him from testifying about LT-4487 and the Kannan and Bonomi-Huvala declarations at trial.

Dated: May 11, 2020

Respectfully submitted,

FARNAN LLP

/s/ Brian E. Farnan

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Inc., Par Sterile Products, LLC, and Endo
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CERTIFICATION OF COMPLIANCE

The foregoing document complies with the type-volume limitation of this Court's March 2, 2020 form Scheduling Order For All Cases where Infringement is Alleged. The text of this brief, including footnotes, was prepared in Times New Roman, 14 point. According to the word processing system used to prepare it, the brief contains 702 words, excluding the case caption, signature block, table of contents and table of authorities.

/s/ Brian E. Farnan

Brian E. Farnan (Bar No. 4089)

Dated: May 11, 2020

EXHIBIT A

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

PAR PHARMACEUTICAL, INC., PAR
STERILE PRODUCTS, LLC, and ENDO
PAR INNOVATION COMPANY, LLC,
Plaintiffs,

v.

EAGLE PHARMACEUTICALS INC.,
Defendant.

C.A. No. 18-00823-CFC



REPLY EXPERT REPORT OF KINAM PARK, PH.D.

efficacy and shelf-life. *See, e.g.*, Kannan Dep. 187:22–188:22; Vandse Dep. 254:16–22; Sanghvi Dep. 146:21–147:5, 148:14–149:8, 150:13–18, 151:3–22.

25. In addition, Dr. Kirsch's assertion that [REDACTED] is simply wrong.

Kirsch Rebuttal ¶ 168–69. Dr. Kirsch relies [REDACTED]

[REDACTED] But even Dr. Kirsch admits that [REDACTED]

[REDACTED] *See, e.g.*, AR3-VASO-0000012; Kirsch Rebuttal ¶¶ 146, 151, 173, 178. Dr. Kirsch's reliance on [REDACTED]

[REDACTED] If Dr. Kirsch is right that [REDACTED]

[REDACTED] then this further confirms that information about the narrower, optimized pH ranges in the prior art, as seen with Pitressin® and Vasostriect®, were material to the patentability of Par's patents, despite being withheld by the inventors who were aware of it.

26. I note that other researchers also sought to prepare stable formulations of vasopressin using particular pH targets, contrary to Dr. Kirsch's argument that [REDACTED]. For example, prior art Lithuanian Patent No. 4487 (PAR-VASO_0233012–22) teaches a target pH range of 3.80 to 3.95 in the manufacture of a vasopressin injection composition. PAR-VASO_0233014. This is a relatively narrow pH target, encompassing the claimed pH values, that evidences work to optimize the pH-dependent stability of vasopressin formulations.

are the same impurities that are called out in the dependent claims of the '209 and '785 patents and are considered in determining whether a formulation meets the 0.9 to 1.7% impurity requirements. Thus, this same analysis applies to the impurity limitations of the '209 and '785 patents.

150. Dr. Kirsch undercuts his infringement analysis by stating that [REDACTED] with [REDACTED] regard to impurities. Kirsch Rebuttal ¶ 158. [REDACTED]

[REDACTED]

[REDACTED]

VI. THE WITHHELD PRIOR ART REFERENCES AND INFORMATION ARE MATERIAL

151. I understand that a preponderance of the evidence standard is applied by the examiner during the prosecution of applications before the Patent and Trademark Office. Furthermore, I understand that the burden of proving infringement is also a preponderance of the evidence.

A. The False Declarations Regarding the April 2014 Vasostrict® Label Are Material

152. As set forth in my opening report, the April 2014 Vasostrict® Label was excluded as prior art during prosecution of the '239 patent (and later during prosecution of the remaining patents-in-suit) solely because of the Kannan and Bonomi-Huvala Declarations, which represented that Vinayagam Kannan and Matthew Kenney invented the subject matter of the April 2014 Vasostrict® Label cited by the Examiner in her rejection. These Declarations were false, however, and the inventors did not invent that subject matter.

153. Dr. Kirsch recognizes that [REDACTED]

[REDACTED] Kirsch

Rebuttal ¶¶ 289–90. Dr. Kirsch does not, however, [REDACTED]

[REDACTED]

The Declarations led the Examiner to remove a final rejection of the pending claims over the April 2014 Vasostrict® Label. In addition, because the '209, '526, and '785 patents are each continuations-in-part of the '239 patent and named both of the inventors of that patent, those false declarations also tainted the prosecution of the asserted patents as the Examiner believed she could not rely on the April 2014 Vasostrict® Label as prior art. The Declarations were material to the prosecution of those patents as well.

154. To the extent criticality is relevant to whether the April 2014 Vasostrict® Label is material prior art, I rely on the analysis set forth above, in my Opening Report, and in Dr. Chyall's Opening and Reply Reports and conclude that the inventors could not have shown criticality over this reference had it been relied on as prior art during prosecution.

1. '239 Patent

155. Because the Declarations were false, I understand that they are considered material to the prosecution of the '239 patent.

156. Dr. Kirsch's only argument as to why the April 2014 Vasostrict® Label was not material to the '239 patent claims is that [REDACTED]

[REDACTED] This argument is contradicted by the fact that the Examiner specifically found that the Label inherently disclosed the degradation products limitations of the all of the claims. PAR-VASO-0008327. The same reasoning that the Examiner applied to the specific degradation products levels would also apply to the broader degradation products limitation that Dr. Kirsch discusses. Therefore, if the Examiner had not been persuaded to disqualify the April 2014 Vasostrict® Label as prior art on false pretenses, the claims of the '239 patent as amended would not have issued.

Dated: January 20, 2020

A handwritten signature in black ink, reading "Kinam Park". The signature is written in a cursive style with a large, looped "P".

Kinam Park, Ph.D.

EXHIBIT B

Roberts, Daniel

From: Kwon, Sam <sam.kwon@kirkland.com>
Sent: Wednesday, November 20, 2019 5:54 PM
To: Greene, Blake; Rhoad, Robert; Cade, Ashley; Gagliardi, Sharon; Gribbin, Joe; Goldberg, Brian
Cc: #EagleVasopressinLitigation; ALL NA Endo Vasopressin; *sobyne@potteranderson.com; *dmoore@Potteranderson.com1; *bpalapura@potteranderson.com; EXT Michael Farnan; EXT Brian Farnan
Subject: RE: Par Sterile Products, LLC, et al. v. Eagle Pharmaceuticals, Inc. -- Par's Interrogatory Responses
Attachments: Park Opening Report Appendix 5 - Publication Obviousness.PDF

Blake,

We write to follow up on the parties' meet and confer regarding Par's request for an extension to the scheduling order. On the meet and confer, you articulated two bases that allegedly necessitate Par's proposed adjustment to the case schedule: (1) that the expert report of Dr. Kinam Park relies on certain references that were not disclosed in Eagle's contentions; and (2) that one of Par's experts and some of Par's counsel have limited availability in December.

On the first basis, the references that we believe you identified on the call—Gibson, Fenton, Fox, and Yoshioka/Stella—are merely cited as background information and are not part of Dr. Park's invalidity analysis, and not as part of any obviousness combination. Nevertheless, to eliminate any ambiguity and any alleged prejudice Par might claim to suffer from the inclusion of these references in Dr. Park's report, Eagle is hereby removing the references from Dr. Park's Appendix 5 (see revised Appendix 5 attached), and will also agree that Dr. Park will not rely on those references to support his invalidity opinions in any way. This eliminates the only basis in the reports themselves you identified as allegedly causing Par prejudice and necessitating an extension. If Par believes there are other bases for alleged prejudice in Eagle's expert reports, please let us know immediately.

On the second basis, you have not provided any information regarding the purported conflicts, including which expert and counsel have the conflict, what the cause of the conflict is, and over what time period they are conflicted. Please provide that information immediately so that Eagle may evaluate whether there is any basis for Par to claim that these conflicts are somehow more onerous than the conflicts that Eagle's counsel would suffer as identified on the call (including trial and other case conflicts, and childbirth) as a result of Par's proposed revised schedule, particularly given the size of Par's case team.

Finally, please let us know if there are any other bases that Par believes support its proposed extension so that Eagle may fully evaluate its position prior to Par prematurely bringing this issue to the Court.

Regards,
Sam

Sam Kwon

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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**


PAR PHARMACEUTICAL, INC.,)	
PAR STERILE PRODUCTS, LLC, and)	
ENDO PAR INNOVATION)	
COMPANY, LLC,)	
)	C.A. No. 18-823-CFC
Plaintiffs,)	
)	
v.)	
)	
EAGLE PHARMACEUTICALS INC.,)	
)	
Defendant.)	

EXHIBIT 15.1.2

**DEFENDANT'S OPPOSITION TO
PLAINTIFFS' MOTION *IN LIMINE* NO. 1**

Par's motion to exclude certain of Dr. Park's reply opinions should be denied because the identified opinions were not new and appropriately replied to arguments raised for the first time in Par's expert Dr. Kirsch's rebuttal report.

First, Par misrepresents Dr. Park's opinions on Lithuanian Patent 4487, which were offered in direct response to Par's new assertions regarding the state of the art. "Reply reports 'may cite new evidence and data [where] offered to directly contradict or rebut the opposing party's expert.'" *Helios Software, LLC v. SpectorSoft Corp.*, 2014 WL 4796111, at *3 (D. Del. Sept. 18, 2014) (citation omitted). Par asserted for the first time, via Dr. Kirsch's rebuttal report, that [REDACTED]

[REDACTED] Dr. Park cited LT-4487 in response, explaining that it "evidences work to optimize the pH-dependent stability of vasopressin formulations" and "teaches a target pH range of 3.80 to 3.95." (Ex. 1 ¶¶ 25–26, 32.) Dr. Park did not rely on it in a new obviousness combination as Par suggests.¹

The *Pennypack* factors do not support exclusion. Even if Par were prejudiced—which it has not shown—it "had ample opportunity to prepare for Dr.

¹ Par's reference to Eagle's "Section 282 disclosures" is puzzling as they have not yet been served. 35 U.S.C. § 282(c) (due 30 days before trial). If Par is referring to Eagle's Disclosure of Invalidity References, it was served months before Dr. Kirsch's new rebuttal opinions.

[Park]’s deposition and, in fact, questioned him about [LT-4487],” including “public accessibility” and “the significance and extent of differences” between naturally derived and synthetic vasopressin (Ex. 2 at 147:16-159:4).² *INVISTA N.A. S.a.r.l. v. M&G USA Corp.*, 2013 WL 3216109, at *2 (D. Del. June 25, 2013) (denying motion to strike). Nor has Par shown that Dr. Park’s reliance on LT-4487 will disrupt trial or that Eagle acted in bad faith or willfully. Finally, LT-4487 is important to Eagle, as it directly refutes Dr. Kirsch’s incorrect—and late-disclosed—factual contention. *See id.* (considering “the importance of the evidence to the proffering party”).³ If Dr. Park cannot rely on LT-4487, Dr. Kirsch’s previously undisclosed opinion that that POSAs believed pH to be unimportant and were discouraged from using a pH other than 3.4-3.6 should also be excluded.

Second, Dr. Park’s reply opinions regarding the false Kannan and Bonomi-Huvala Declarations—that the Examiner relied on to disqualify the April 2014 Vasostrict® label as prior art—were not new. In his opening report, Dr. Park opined that the inventors “did not invent, develop, or contribute to” the formulation in the disqualified label, despite the Declarations’ contrary assertions. (Ex. 3 ¶¶77,

² Unlike Dr. Kirsch who refused to explain his opinions regarding Eagle’s alleged intent to induce infringement—raised for the first time in his reply report (*see* Eagle’s MIL No. 2 at 2-3)—Dr. Park answered Par’s counsel’s questions fulsomely.

³ Par inexplicably excludes “importance” from the *Pennypack* factors to be considered on its Motion. (Par Mot. at 1.)

271.) He also said he was “asked to opine on the materiality of prior art that was withheld *or excluded based on statements made during prosecution by the inventors.*” (*Id.* ¶377 (emphasis added).) Indeed, Dr. Park explained over 30 paragraphs why the disqualified label would have been material to the prosecutions of the ’239 patent and the Patents-in-Suit. (*Id.* ¶¶378-408.)

Par does not suggest Dr. Kirsch was unaware these opinions related to materiality and impact of the false Declarations. (*See* Par Mot. at 2.) On the contrary, Dr. Kirsch acknowledged [REDACTED] [REDACTED] (Ex. 4 ¶¶289-90.)

And he addressed Dr. Park’s (and Dr. Chyall’s) materiality opinions in detail. (*Id.* ¶¶401-11.) Par’s complaint seems merely to be that Dr. Park did not describe his opinions on the false Declarations on reply with the exact same words as in opening. But that does not warrant exclusion, as experts are entitled to “reasonable . . . elaboration on opinions [they] adequately disclosed as well as appropriate rebuttal testimony.” *Noven Pharm., Inc. v. Actavis Labs. UT, Inc.*, 2017 WL 319238, at *1 (D. Del. Jan. 19, 2017) (first alteration in original) (citation omitted).

Finally, Par cannot show the *Pennypack* factors warrant exclusion because it has not alleged, much less shown, incurable prejudice. (Par Mot. at 3 (identifying

alleged prejudice only for LT-4487).) Nor has it alleged potential trial disruption, bad faith, or willfulness.

Par's motion should be denied.

Date: May 11, 2020

POTTER ANDERSON & CORROON LLP

By: /s/ Bindu A. Palapura

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CERTIFICATION OF COMPLIANCE

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Date: May 11, 2020

/s/ Bindu A. Palapura
Bindu A. Palapura (Bar No. 5370)

EXHIBIT 1

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

PAR PHARMACEUTICAL, INC., PAR
STERILE PRODUCTS, LLC, and ENDO
PAR INNOVATION COMPANY, LLC,
Plaintiffs,

v.

EAGLE PHARMACEUTICALS INC.,
Defendant.

C.A. No. 18-00823-CFC



REPLY EXPERT REPORT OF KINAM PARK, PH.D.

efficacy and shelf-life. *See, e.g.*, Kannan Dep. 187:22–188:22; Vandse Dep. 254:16–22; Sanghvi Dep. 146:21–147:5, 148:14–149:8, 150:13–18, 151:3–22.

25. In addition, Dr. Kirsch's assertion that [REDACTED] is simply wrong. Kirsch Rebuttal ¶ 168–69. Dr. Kirsch relies on [REDACTED] But even Dr. Kirsch admits that [REDACTED] *See, e.g.*, AR3-VASO-0000012; Kirsch Rebuttal ¶¶ 146, 151, 173, 178. Dr. Kirsch's reliance on [REDACTED] If Dr. Kirsch is right that [REDACTED] then this further confirms that information about the narrower, optimized pH ranges in the prior art, as seen with Pitressin® and Vasostriect®, were material to the patentability of Par's patents, despite being withheld by the inventors who were aware of it.

26. I note that other researchers also sought to prepare stable formulations of vasopressin using particular pH targets, contrary to Dr. Kirsch's argument that [REDACTED] For example, prior art Lithuanian Patent No. 4487 (PAR-VASO_0233012–22) teaches a target pH range of 3.80 to 3.95 in the manufacture of a vasopressin injection composition. PAR-VASO_0233014. This is a relatively narrow pH target, encompassing the claimed pH values, that evidences work to optimize the pH-dependent stability of vasopressin formulations.

27. In all of my experience in the field, I am not aware of any circumstance where a manufacture would pick out such specific targets within a range on a whim. Instead, these efforts indicate that the very people who were formulating vasopressin in the field—*i.e.*, POSAs—were carrying out routine optimization of the USP vasopressin formulation to identify a product with maximum stability. Dr. Kirsch never addresses these narrower pH targets in the prior art.

B. pH Limitations of the Asserted Claims Are Obvious

28. Dr. Kirsch does not dispute that the prior art disclosed a pH range of 2.5 to 4.5 for vasopressin products, including in the labels for PPC's, American Regent's, and Fresenius's vasopressin products, as well as the USP standard. This range encompasses the claimed values completely and, therefore, I understand that those claimed values are presumptively obvious. The burden is therefore on Par to demonstrate that these pH values exhibit surprising and unexpected results over this prior art to establish criticality. As I have explained, Par cannot do so.

29. In addition, I understand that the abutting 3.7–3.9 prior art pH range of the '209 and '785 patents is also presumptively obvious over the pH range of 3.4 to 3.6 used for Vasostrict® and Pitressin® and shown in the Vasostrict® label and, again, the burden is on Par to establish criticality.

1. POSAs Would Have Had A Reasonable Expectation of Success in Making the Claimed Inventions

30. Dr. Kirsch's primary argument regarding the pH limitations is that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Kirsch Rebuttal ¶¶ 177–78. This contention is confusing, because it contradicts Dr.

Kirsch's assertion [REDACTED]

[REDACTED] Kirsch Rebuttal ¶ 176.

31. Furthermore, if Dr. Kirsch is correct that [REDACTED] [REDACTED] then there would be no merit to the claimed inventions and, of course, no criticality or unexpected results over the prior art. In that regard, I reiterate that there is no evidence that the claimed formulations led to any practical benefits, including safety, efficacy or shelf life benefits over these prior art formulations, that resulted from the purportedly inventive work undertaken by the named inventors, but this merely confirms the obviousness of the claimed pH values.

32. Based on his opinion that [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] Kirsch Rebuttal ¶ 173. I do not agree with that contention. First, it is not correct that POSAs would have expected the pH range of 3.4–3.6 to be the exclusive stable pH. To the contrary, as I discussed in my Opening Report, and set out herein, POSAs specifically manufactured vasopressin formulations at the claimed pHs values. *See, e.g., supra* Part III.A; *infra* Part IV.

33. Second, Dr. Kirsch's opinion that [REDACTED]

[REDACTED]
[REDACTED] The claimed pH range of 3.7–3.9 directly abuts the Pitressin and Vasostrict's pH of 3.4–3.6. Further, the allegedly "critical" pH of 3.8 is just two tenths of pH unit away from the prior art pH of 3.6. Because the claimed pHs that

are so close to the prior art's range, POSAs would have had a reasonable expectation of success that the claimed pHs would too be stable. Dr. Kirsch implicitly agrees to this when opining that

[REDACTED]

[REDACTED] Kirsch Rebuttal ¶ 348. Here, there is no evidence of any dramatic or actual difference in stability of the claimed pHs from the prior art's pH of 3.4-3.6 in part because they are so near one another, and that is exactly what POSAs would have reasonably expected.

34. Dr. Kirsch has not provided any contrary evidence, including any evidence that the stability of vasopressin at pH 3.8 is unexpectedly improved over pH 3.6. In fact, Dr. Kirsch has not provided any evidence suggesting that pH 3.8 has any improved stability over pH 3.8. If there indeed exists an actual difference between the claimed pH and the prior art pH, there is no evidence that such difference is unexpected or confers a real or practical benefit in clinical practice.

35. Therefore, it is my opinion that based on Dr. Kirsch's assertions that [REDACTED]

[REDACTED]

[REDACTED] it necessarily follows that POSAs would have had a reasonable expectation of success in creating stable vasopressin formulations targeted at the claimed pH.

36. Dr. Kirsch attempts to magnify these small differences over the prior art by focusing on [REDACTED] Kirsch Rebuttal ¶¶ 28, 157, 176, 188. Such discussion, however, ignores practical implications. POSAs rely on the pH, [REDACTED]

[REDACTED]

[REDACTED]

Dated: January 20, 2020

A handwritten signature in black ink, reading "Kinam Park". The signature is written in a cursive style with a large, looped "P".

Kinam Park, Ph.D.

EXHIBIT 2

1 UNITED STATES DISTRICT COURT
2 DISTRICT OF DELAWARE

3 -----x

4 PAR PHARMACEUTICAL, INC.,
5 PAR STERILE PRODUCTS, LLC and
6 ENDO Par INNOVATION COMPANY, LLC,
Plaintiffs,

Civil Action No.

7 -against-

18-823-CFC

8 EAGLE PHARMACEUTICALS,
9 Defendant.

10 -----x

11 February 18, 2020

9:04 a.m.

12
13 
14 PURSUANT TO PROTECTIVE ORDER

15
16
17 Videotaped Deposition of DR. KINAM PARK,
18 PH.D, taken by Plaintiff, pursuant to Notice, at
the offices of Kirkland & Ellis, LLP, 601
19 Lexington Avenue, New York, New York, before
William Visconti, a Shorthand Reporter and Notary
20 Public within and for the State of New York.
21
22
23
24
25

<p style="text-align: right;">Page 2</p> <p>1 APPEARANCES:</p> <p>2 DECHERT LLP</p> <p>3 Attorneys for Plaintiffs</p> <p>4 3000 El Camino Real</p> <p>5 Five Palo Alto Square</p> <p>6 Palo Alto, CA 94306</p> <p>7 BY: JONATHAN LOEB, ESQ.</p> <p>8 jonathan.loeb@dechert.com</p> <p>9 BLAKE GREENE, ESQ.</p> <p>10 (Austin Office.)</p> <p>11 blake.greene@dechert.com</p> <p>12</p> <p>13 KIRKLAND & ELLIS LLP</p> <p>14 Attorneys for Defendant</p> <p>15 601 Lexington Avenue</p> <p>16 New York, NY 10022</p> <p>17 BY: BENJAMIN LASKY, ESQ.</p> <p>18 blasky@kirkland.com</p> <p>19</p> <p>20 ALSO PRESENT:</p> <p>21 CARLOS KING, Videographer</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 4</p> <p>1 THE VIDEOGRAPHER: Good morning.</p> <p>2 We are going on record at 9:04 a.m. on</p> <p>3 February 18th, 2020. Please note that the</p> <p>4 microphones are sensitive and may pick up</p> <p>5 whispering, private conversations and</p> <p>6 cellular interference. Please turn off</p> <p>7 cell phones and place them away from the</p> <p>8 microphones as they can interfere with the</p> <p>9 deposition audio. Audio and video</p> <p>10 recording will continue to take place</p> <p>11 unless all parties agree to go off the</p> <p>12 record.</p> <p>13 This is media unit one of the video</p> <p>14 recorded deposition of Dr. Kinam Park taken</p> <p>15 by counsel for Plaintiffs in the matter of</p> <p>16 Par Pharmaceuticals, Inc., et al., versus</p> <p>17 Eagle Pharmaceuticals Inc. filed in United</p> <p>18 States District Court for the District of</p> <p>19 Delaware civil action number</p> <p>20 18-00823-(CFC).</p> <p>21 This deposition is being held at the</p> <p>22 offices of Kirkland & Ellis located at 601</p> <p>23 Lexington Avenue, New York, New York. My</p> <p>24 name is Carlos King from the firm of</p> <p>25 Veritext, I'm a videographer. The court</p>
<p style="text-align: right;">Page 3</p> <p>1 IT IS HEREBY STIPULATED AND AGREED</p> <p>2 by and between the attorneys for the</p> <p>3 respective parties herein that filing and</p> <p>4 sealing be and the same are hereby waived.</p> <p>5 IT IS FURTHER STIPULATED AND AGREED</p> <p>6 that all objections, except as to the form</p> <p>7 of the question, shall be reserved to the</p> <p>8 time of the trial.</p> <p>9 IT IS FURTHER STIPULATED AND AGREED</p> <p>10 that the within deposition may be signed</p> <p>11 and sworn to before any officer authorized</p> <p>12 to administer an oath with the same force and</p> <p>13 effect as if signed and sworn to before the</p> <p>14 Court.</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 5</p> <p>1 reporter is Mr. William Visconti also from</p> <p>2 Veritext.</p> <p>3 I'm not authorized to administer</p> <p>4 nor am I related to any party in this</p> <p>5 action or am I financially interested in</p> <p>6 the outcome.</p> <p>7 Counsel and all present in the room</p> <p>8 and anyone attending remotely will state</p> <p>9 their appearance and affiliations for the</p> <p>10 record. If there are any objections to the</p> <p>11 proceedings please state them at the time</p> <p>12 of your appearance beginning with the</p> <p>13 noticing attorney.</p> <p>14 MR. LOEB: I'm Jonathan Loeb, I'm</p> <p>15 with Dechert LLP in Palo Alto, California</p> <p>16 and I represent the Plaintiffs Par</p> <p>17 Pharmaceutical, et al. with me here today</p> <p>18 is my colleague Blake Greene, he is also of</p> <p>19 Dechert LLP.</p> <p>20 MR. LASKY: I'm Benjamin Lasky from</p> <p>21 Kirkland & Ellis LLP and I represent the</p> <p>22 Defendant and the witness.</p> <p>23 THE VIDEOGRAPHER: Can the court</p> <p>24 reporter please swear the witness.</p> <p>25</p>

<p style="text-align: right;">Page 146</p> <p>1 relying on some typographical error for the</p> <p>2 question that I'm going to ask Dr. Park.</p> <p>3 In any event your objection is noted.</p> <p>4 Q. Down at line 18 on page 212 it</p> <p>5 says "And for example, vasopressin as used in</p> <p>6 the assert claims was not derived from an</p> <p>7 animal or human, right?" And then Dr. Amiji</p> <p>8 answered, "No, the vasopressin as described in</p> <p>9 the patents is a synthetic molecule and it is</p> <p>10 supplied as arginine vasopressin."</p> <p>11 Do you agree with Dr. Amiji that</p> <p>12 the vasopressin described in the patent is a</p> <p>13 synthetical molecule and it is supplied as</p> <p>14 arginine vasopressin?</p> <p>15 MR. LASKY: Objection to the form</p> <p>16 and same objections that I stated</p> <p>17 previously regarding this excerpt of the</p> <p>18 document. It even has the next question</p> <p>19 cut off.</p> <p>20 (Witness reviewing document.)</p> <p>21 Q. Dr. Park --</p> <p>22 MR. LASKY: He is reviewing.</p> <p>23 MR. LOEB: I understand.</p> <p>24 Q. I would like to ask you which</p> <p>25 patent are you reviewing there?</p>	<p style="text-align: right;">Page 148</p> <p>1 A. That's correct.</p> <p>2 Q. In your reply report you identify</p> <p>3 Lithuanian patent 4487 in support of your</p> <p>4 obviousness opinion, correct?</p> <p>5 A. Correct. It talks about pH 3.8.</p> <p>6 Q. Do you have an understanding when</p> <p>7 the Lithuanian patent 4487 was published?</p> <p>8 A. April 26th, 1999.</p> <p>9 Q. Do you have an understanding how</p> <p>10 the Lithuanian patent was published?</p> <p>11 A. I'm not sure I understand your</p> <p>12 question. How it was published?</p> <p>13 Q. Was it published on the internet?</p> <p>14 Was it published in a book? Was it published</p> <p>15 and distributed? What happened when the 4487</p> <p>16 patent was published on the date of the</p> <p>17 publication, 4/26, 1999?</p> <p>18 A. If I understand your question</p> <p>19 correctly, the median of the publication is my</p> <p>20 understanding that it was published in</p> <p>21 Lithuania, so this particular document is a</p> <p>22 certified translation of the patent.</p> <p>23 Q. Now, I just want to talk about the</p> <p>24 actual Lithuanian patent. I understand this is</p> <p>25 a translation.</p>
<p style="text-align: right;">Page 147</p> <p>1 A. '526.</p> <p>2 Q. Thank you.</p> <p>3 A. They are pretty much the same</p> <p>4 anyway, right?</p> <p>5 Q. Yes, I wanted to make sure that we</p> <p>6 were looking at the same thing.</p> <p>7 (Witness reviewing document.)</p> <p>8 A. So the question is whether I agree</p> <p>9 with him or not?</p> <p>10 Q. Yes.</p> <p>11 A. I recall that the peptides used</p> <p>12 was synthesized, so I agree with him.</p> <p>13 (Park Exhibit 18 for identification,</p> <p>14 Document Bates PAR-VASO_0233012 through</p> <p>15 022.)</p> <p>16 Q. You have just been handed</p> <p>17 Exhibit 18 to your deposition. It's a</p> <p>18 Lithuanian patent description entitlement --</p> <p>19 numbered LT 4487 B and it has the Bates numbers</p> <p>20 PAR-VASO_0233012 through 022. Do you have that</p> <p>21 in front of you?</p> <p>22 A. Yes.</p> <p>23 Q. Do you recognize this Lithuanian</p> <p>24 patent is the one which you discuss briefly in</p> <p>25 your reply report?</p>	<p style="text-align: right;">Page 149</p> <p>1 Do you have any understanding of</p> <p>2 to whom the Lithuanian patent was distributed</p> <p>3 to when it was published?</p> <p>4 A. I'm sorry, I don't quite</p> <p>5 understand the question. Published to whom.</p> <p>6 Q. Who had access to the Lithuanian</p> <p>7 patent when it was published?</p> <p>8 MR. LASKY: Objection to the form.</p> <p>9 A. Prior art is such as long as it is</p> <p>10 published we presume that everybody has access</p> <p>11 to it.</p> <p>12 Q. I'm actually asking you about who</p> <p>13 had access to this. Not presuming anything,</p> <p>14 but what you know, who had access to the</p> <p>15 Lithuanian patent when it was published?</p> <p>16 MR. LASKY: Objection to the form.</p> <p>17 Asked and answered.</p> <p>18 A. I don't know exactly who got</p> <p>19 access, but as long as it was published it was</p> <p>20 in the public domain and that's what I got.</p> <p>21 Q. Now, you mentioned the median of</p> <p>22 the publication. Do you have an understanding</p> <p>23 of what the median that the Lithuanian patent</p> <p>24 was published in?</p> <p>25 A. I guess it was print at least.</p>

<p style="text-align: right;">Page 150</p> <p>1 Q. You guess or you know?</p> <p>2 MR. LASKY: Objection to the form.</p> <p>3 A. It has to be printed first of all</p> <p>4 so it was printed and year 1999 we are already</p> <p>5 in the Internet age, so I'm not sure if there</p> <p>6 are any electronic documents on there. But</p> <p>7 again, it was published, it was in the public</p> <p>8 domain. So anybody can have access to it.</p> <p>9 Q. So you said it was printed.</p> <p>10 What's your basis for your testimony that the</p> <p>11 Lithuanian patent 4487 was printed as of</p> <p>12 April 26th, 1999?</p> <p>13 A. I think publication means printed</p> <p>14 before the internet era usually printed and</p> <p>15 that's the publication date. In our days we</p> <p>16 still call it publication date, but that</p> <p>17 sometimes indicates publication on the</p> <p>18 internet. But I think in 1999 even still today</p> <p>19 when we call it publication, it usually means</p> <p>20 printed form too.</p> <p>21 Q. Did you investigate what the State</p> <p>22 Patent Bureau of Lithuania's practices were in</p> <p>23 1999 concerning publication of patents?</p> <p>24 A. I don't know, but all I know is</p> <p>25 that it was published in April 26th, 1999 and</p>	<p style="text-align: right;">Page 152</p> <p>1 MR. LASKY: Objection, calls for</p> <p>2 legal conclusion, outside the scope.</p> <p>3 A. That is something I will refer to</p> <p>4 counsel to figure it out. But the pH of 3.8,</p> <p>5 this is one example, but as I mentioned before,</p> <p>6 American Regent has a pH of 3.8 already.</p> <p>7 Q. Dr. Park, did you identify the</p> <p>8 Lithuanian patent through your own independent</p> <p>9 research?</p> <p>10 A. No.</p> <p>11 Q. It was provided to you by counsel?</p> <p>12 A. I worked with counsel.</p> <p>13 Q. It was provided to you by counsel?</p> <p>14 A. I'm not sure exactly what you mean</p> <p>15 by provided. I work with counselor and I</p> <p>16 obtained this document.</p> <p>17 Q. From Eagle's counsel; correct?</p> <p>18 A. Correct.</p> <p>19 Q. Now, in all of your long years of</p> <p>20 experience working in drug development, have</p> <p>21 you ever reviewed a Lithuanian patent for</p> <p>22 guidance in any of your projects?</p> <p>23 MR. LASKY: Objection to the form.</p> <p>24 Misleading.</p> <p>25 A. I'm not sure why that is even</p>
<p style="text-align: right;">Page 151</p> <p>1 since then it's public information.</p> <p>2 Q. Did you investigate who had access</p> <p>3 to the Lithuanian patent 4487 as of April of</p> <p>4 1999?</p> <p>5 MR. LASKY: Objection to the form.</p> <p>6 Asked and answered.</p> <p>7 A. Again, I don't know who had access</p> <p>8 in 1999. Certainly 2020 we have the document</p> <p>9 here.</p> <p>10 Q. Now, the publication date in 1999</p> <p>11 predates the filing date of the asserted</p> <p>12 patents by more than 16 years; is that correct?</p> <p>13 A. Almost 16 years, yes.</p> <p>14 Q. Now, you did not mention the</p> <p>15 Lithuanian patent in either your opening report</p> <p>16 or your noninfringement report, correct?</p> <p>17 A. I don't think I did. But later I</p> <p>18 mentioned.</p> <p>19 Q. Now, Dr. Kirsch had his</p> <p>20 opportunity to respond to your noninfringement</p> <p>21 arguments in his rebuttal report, correct?</p> <p>22 A. Yes.</p> <p>23 Q. But he hasn't had an opportunity</p> <p>24 to respond to your opinions that were first</p> <p>25 presented in your reply report, correct?</p>	<p style="text-align: right;">Page 153</p> <p>1 relevant. The fact is that published document</p> <p>2 is in the public domain and anybody had access</p> <p>3 to it. So whether it is in Lithuania or China</p> <p>4 or Mongolia, somewhere in Africa, as long as it</p> <p>5 is published it is presumed to be a prior art.</p> <p>6 Q. Respectfully, that wasn't my</p> <p>7 question. I simply asked you in the course of</p> <p>8 your research have you ever utilized a</p> <p>9 Lithuanian patent publication for any purpose?</p> <p>10 MR. LASKY: Objection, asked and</p> <p>11 answered.</p> <p>12 A. It was not necessarily before, but</p> <p>13 now I do, so here we have.</p> <p>14 Q. I asked you about your research.</p> <p>15 Your scientific research, doctor. In the</p> <p>16 course of your scientific research, have you</p> <p>17 ever relied on information that you obtained</p> <p>18 from a Lithuanian patent?</p> <p>19 MR. LASKY: Objection to the form.</p> <p>20 Same objections, asked and answered.</p> <p>21 A. In my research I go through</p> <p>22 literature search through the search engines in</p> <p>23 the publishers and through public libraries and</p> <p>24 you go through electronic search, not only</p> <p>25 Lithuania but anywhere in the world including</p>

<p style="text-align: right;">Page 154</p> <p>1 Africa, all the information shows up. So I</p> <p>2 don't particularly look for certain country. I</p> <p>3 look for topics.</p> <p>4 Q. It is not a hypothetical question</p> <p>5 that I'm asking, Dr. Park. I'm asking you a</p> <p>6 factual question. In all of your years of</p> <p>7 conducting scientific research, have you ever</p> <p>8 relied on a Lithuanian patent for any purpose?</p> <p>9 MR. LASKY: Objection, asked and</p> <p>10 answered. Same objections as before.</p> <p>11 A. I will have the same answer.</p> <p>12 Because I don't look for certain country. I</p> <p>13 look for the topic and look for the relevant</p> <p>14 papers and then there may be Lithuania. I</p> <p>15 don't remember.</p> <p>16 Q. You don't remember?</p> <p>17 A. Right.</p> <p>18 Q. Okay.</p> <p>19 Can I have you look at the</p> <p>20 Lithuanian patent, Exhibit 18, on the second</p> <p>21 page of the document. If you look at the very</p> <p>22 last sentence on the second page of the</p> <p>23 document it states "The active ingredients</p> <p>24 arginine vasopressin is excreted from animal</p> <p>25 posterior lobe pituitary extract purified by</p>	<p style="text-align: right;">Page 156</p> <p>1 acids is exactly the same as synthetic arginine</p> <p>2 vasopressin. And that has to be because</p> <p>3 chemical structure must be the same.</p> <p>4 Q. If you look at the next sentence</p> <p>5 after the chemical structure on the page ending</p> <p>6 in 14, it states "The absence of the invention</p> <p>7 is that the following components are included</p> <p>8 in the preparation produced from an active</p> <p>9 ingredient derived from animal posterior lobe</p> <p>10 pituitary extract and in the preservative." Do</p> <p>11 you see that?</p> <p>12 A. Yes.</p> <p>13 Q. So the inventors of the Lithuanian</p> <p>14 patent stated that the essence of the invention</p> <p>15 were the components that were included with</p> <p>16 active ingredient derived from animal posterior</p> <p>17 lobe pituitary extract, correct?</p> <p>18 MR. LASKY: Objection to the form.</p> <p>19 A. It states "The following</p> <p>20 components are included in the preparation</p> <p>21 produced from an active ingredient derived from</p> <p>22 animal posterior lobe pituitary gland." So</p> <p>23 they isolated and purified using HPLC and then</p> <p>24 they added other components.</p> <p>25 Q. Now the Lithuanian patent does not</p>
<p style="text-align: right;">Page 155</p> <p>1 high performance chromatography (HPLC)." Do you</p> <p>2 see that?</p> <p>3 A. Yes.</p> <p>4 Q. So the particular vasopressin</p> <p>5 formulation disclosed in the Lithuanian patent</p> <p>6 used naturally derived arginine vasopressin,</p> <p>7 correct?</p> <p>8 MR. LASKY: Objection to the form.</p> <p>9 A. Naturally derived arginine</p> <p>10 vasopressin at the same chemical structure as</p> <p>11 the synthesized vasopressin.</p> <p>12 Q. Do you have an understanding</p> <p>13 whether or not the naturally derived</p> <p>14 vasopressin which was used by the Lithuanian</p> <p>15 patent inventors had the same impurity profile</p> <p>16 as the synthetic vasopressin that is described</p> <p>17 in the patents-in-suit?</p> <p>18 MR. LASKY: Objection to the form.</p> <p>19 A. I don't see the exact details of</p> <p>20 impurities, but the sentence uses where it</p> <p>21 clearly said "purified by a high performance</p> <p>22 chromatography" that usually means you purify</p> <p>23 API as much as you can, probably very pure</p> <p>24 level. And also if you look at the next page,</p> <p>25 exact chemical structure, the sequence of amino</p>	<p style="text-align: right;">Page 157</p> <p>1 provide any data concerning the rate of</p> <p>2 degradation that their formulation had during</p> <p>3 storage; correct?</p> <p>4 A. Not that I find. But degradation</p> <p>5 is an inherent property of the formulation. In</p> <p>6 this case including arginine vasopressin.</p> <p>7 Q. All the data that is provided in</p> <p>8 the Lithuanian patent is clinical data, right?</p> <p>9 A. No, page 2 which is Vaso 014 it</p> <p>10 shows the formation data.</p> <p>11 Q. So it is the recipe for their</p> <p>12 formulation?</p> <p>13 A. Right, including pH 3.8, 3.9.</p> <p>14 Q. But the actual data, the</p> <p>15 measurements that are described in the tables</p> <p>16 all relate to clinical use of this formulation;</p> <p>17 correct?</p> <p>18 A. That's right. It shows that they</p> <p>19 are safe and effective.</p> <p>20 Q. Now, the Lithuanian patent does</p> <p>21 not identify any of the impurities which are</p> <p>22 found in the formulation which is described,</p> <p>23 correct?</p> <p>24 MR. LASKY: Objection to the form.</p> <p>25 A. It does not, but again, it was</p>

<p style="text-align: right;">Page 158</p> <p>1 purified by HPLC so we can understand that most</p> <p>2 of the impurities are gone.</p> <p>3 Q. It doesn't describe the amounts of</p> <p>4 any of the impurities that are found during</p> <p>5 storage of the vasopressin formulation as</p> <p>6 described, right?</p> <p>7 A. Again, that is just a matter of</p> <p>8 simple measurement. It's an inherent property.</p> <p>9 Q. So, no, the Lithuanian patent does</p> <p>10 not describe the amounts of impurities that</p> <p>11 accumulate during storage?</p> <p>12 MR. LASKY: Objection to the form.</p> <p>13 Asked and answered.</p> <p>14 A. Again, that was a matter of</p> <p>15 measurement over time. So it's an inherent</p> <p>16 property.</p> <p>17 Q. Are the measurements in here or</p> <p>18 are they not? That is all I'm asking.</p> <p>19 MR. LASKY: Objection.</p> <p>20 A. Sorry?</p> <p>21 Q. Are the measurement of amounts of</p> <p>22 impurities disclosed here in the few pages of</p> <p>23 the Lithuanian patent or no?</p> <p>24 MR. LASKY: Objection to the form.</p> <p>25 Asked and answered.</p>	<p style="text-align: right;">Page 160</p> <p>1 on the analysis of Dr. Amiji, correct?</p> <p>2 A. Based on Dr. Amiji's analysis,</p> <p>3 yes.</p> <p>4 Q. And you agree with Dr. Amiji's</p> <p>5 analysis?</p> <p>6 A. Yes.</p> <p>7 Q. And do you understand that each of</p> <p>8 the asserted patents is a continuation in part</p> <p>9 of the '239 patent?</p> <p>10 A. That's right.</p> <p>11 Q. The '239 patent was filed on</p> <p>12 May 20, 2015, you can see that by looking at</p> <p>13 the face of the patent, Exhibit 8?</p> <p>14 A. May 20th, 2015.</p> <p>15 Q. In your opinion the claims of the</p> <p>16 three asserted patents are not entitled to the</p> <p>17 filing date of the '239 patent; correct?</p> <p>18 MR. LASKY: Objection, outside the</p> <p>19 scope. You can answer.</p> <p>20 A. That's what Dr. Amiji's analysis</p> <p>21 says and I relied on him.</p> <p>22 Q. And you agree with it?</p> <p>23 MR. LASKY: Objection to the form.</p> <p>24 Outside the scope.</p> <p>25 A. Dr. Amiji analyzed and I relied on</p>
<p style="text-align: right;">Page 159</p> <p>1 A. I answered already, it does not</p> <p>2 describe, but amount of impurities is just a</p> <p>3 matter of measurement. So it is inherent</p> <p>4 property.</p> <p>5 MR. LOEB: Off the record, please.</p> <p>6 THE VIDEOGRAPHER: The time is 2:56</p> <p>7 p.m. and this marks the end of media</p> <p>8 unit 4.</p> <p>9 (Recess taken).</p> <p>10 THE VIDEOGRAPHER: The time is 3:09</p> <p>11 p.m. and this begins media unit 5.</p> <p>12 BY MR. LOEB:</p> <p>13 Q. Dr. Park, can I have you find your</p> <p>14 opening report again, that is Exhibit 1 and in</p> <p>15 particular can I have you look at paragraph 34</p> <p>16 which is on page 8? Are you there?</p> <p>17 A. Yes.</p> <p>18 Q. You applied a priority date of</p> <p>19 October 10th, 2016 for the '526 patent, right?</p> <p>20 A. Yes.</p> <p>21 Q. And you applied a priority date of</p> <p>22 February 7th, 2017 for the '209 and '785</p> <p>23 patents?</p> <p>24 A. Yes.</p> <p>25 Q. And you applied those dates based</p>	<p style="text-align: right;">Page 161</p> <p>1 his analysis.</p> <p>2 Q. The reason why the claims of the</p> <p>3 '785 and '209 and '526 patent aren't entitled</p> <p>4 to the filing date of the '239 patent is</p> <p>5 because in Dr. Amiji's opinion the '239 patent</p> <p>6 does not provide adequate support for the</p> <p>7 asserted claims, correct?</p> <p>8 MR. LASKY: Objection to the form.</p> <p>9 Outside the scope.</p> <p>10 A. That is his analysis and that is</p> <p>11 what I was relying on.</p> <p>12 Q. The '239 patent specification is</p> <p>13 similar to that of the asserted patents,</p> <p>14 correct?</p> <p>15 MR. LASKY: Objection to the form.</p> <p>16 A. I'm not sure what you mean by</p> <p>17 similar. But pH range is so different, the</p> <p>18 claim of one of the '239 patent is that pH is</p> <p>19 from 3.5 to 4.1 which is overlapping with the</p> <p>20 original Vasostrict claim of 3.4 to 3.6.</p> <p>21 Q. I wasn't asking about the patent</p> <p>22 claims. I was asking about the patent</p> <p>23 specification which is everything but the</p> <p>24 claim. The path specification of the '239</p> <p>25 patent is similar to the patent specification</p>

EXHIBIT 3

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

PAR PHARMACEUTICAL, INC., PAR
STERILE PRODUCTS, LLC, and ENDO
PAR INNOVATION COMPANY, LLC,
Plaintiffs,

v.

EAGLE PHARMACEUTICALS INC.,
Defendant.

C.A. No. 18-00823-CFC

OPENING EXPERT REPORT OF KINAM PARK, PH.D.

[REDACTED]

75. Par proceeded to file NDA No. 204485 on a non-coverage form of Pitressin® on September 25, 2012. PAR-VASO_0072406. Although the NDA filings give the brand name as “Pitressin®,” I understand that the name of the NDA product was changed at the request of the FDA, and Par chose the name Vasostrict®. *See, e.g.*, PAR-VASO_0077570.

76. Par repeatedly affirmed to the FDA that the only difference between the unapproved Pitressin® product and the product described in NDA No. 204485 the this removal of vasopressin and chlorobutanol ingredient overages. PAR-VASO_0072719; Boesch 30(b)(6) Dep. Tr. 38:20–39:2. Consistent with the NDA product being the unapproved Pitressin® formulation with overages removed, the NDA product comprised: 20 units/mL of vasopressin (0.0377 mg/mL); 5.0 mg/mL chlorobutanol; acetic acid for pH adjustment to pH of 3.4 – 3.6; and water for injection. *E.g.*, PAR-VASO_0072474–75. Although the two formulations differed on [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] PAR-VASO_0105310.

77. Especially given that the Vasostrict® formulation is nothing more than the unapproved Pitressin® formulation, the named inventors of the challenged claims confirmed that they did not invent, develop, or contribute to it. *See, e.g.*, Kannan Dep. Tr. 253:6–254:5, 259:5–13; Kenney Dep. Tr. 18:4–10, 30:21–31:2, 36:20–24, 40:11–17, 41:3–8, 42:10–14, 43:6–12; Sanghvi Dep. Tr. 38:9–22, 203:25–205:4; Vandse Dep. Tr. 260:2–261:14.

78. NDA No. 204485 for Vasostrict® was approved on April 17, 2014. *See, e.g.*, PAR-VASO_0015573–86.

79. On that date, the FDA also approved the April 2014 Vasostrict® Label for vasopressin. *See id.* This label was published in April 2014 and is therefore prior art to the asserted

[REDACTED]

See, e.g., id. (“The package insert remains unchanged from that submitted on April 14, 2014, except for the addition of cold storage conditions.”).

271. Furthermore, I understand that the named inventors of the asserted and/or challenged claims, per their own testimony, did not develop or invent the original formulation of Vasostrict® or contribute to its original NDA filing. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Kannan Dep. Tr. 253:6–16; *see also, e.g., id.* at 253:17–254:5, 259:5–13. Matthew Kenney [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Kenney Deposition Transcript at 18:4–10. Finally, Suketu Sanghvi, another named inventor on three of the asserted patents and Par’s corporate witness, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Sanghvi Dep. Tr. 204:11–205:4.

2. Composition Limitations

272. In addition to the discussion below, Par's allegations [REDACTED] [REDACTED] imply that original Vasostrict® must also have met the limitations of the asserted claims or they are not infringed. [REDACTED] [REDACTED] See, e.g., EAGLEVAS0000076. Because the prior art original Vasostrict® formulation [REDACTED] [REDACTED] original Vasostrict® as sold must either anticipate the composition limitations of the asserted and/or challenged claims or they are not infringed by Eagle's proposed ANDA product.

a. Unit Dosage Form

273. Original Vasostrict® was formulated as a 1 mL unit dosage form. See, e.g., PAR-VASO_0072474; PAR-VASO_0072478; September 2014 Vasostrict® Label § 11²⁰; April, 2014 Vasostrict® Label § 11; March 2015 Vasostrict® Label § 11²¹.

²⁰ I understand this Label was approved in September 2014 and was distributed with original Vasostrict® when it was first sold in November 2014. See, e.g., Par's Resps. Interrogs. No. 5, 10.

²¹ I understand this Label was approved in May 2015 by the FDA and distributed with Vasostrict® thereafter. See, e.g., Par's Resps. Interrogs. No. 5, 10.

- September 2014 Vasostrict® Label (anticipation);
- September 2014 Vasostrict® Label, alone or in combination with Intravenous Medications 2013, Russell 2008, Treschan 2006, and/or WO '907 (obviousness);
- March 2015 Vasostrict® Label (anticipation);
- March 2015 Vasostrict® Label, alone or in combination with Intravenous Medications 2013, Russell 2008, Treschan 2006, and/or WO '907 (obviousness);
- PPC, alone or in combination with Intravenous Medications 2013, Russell 2008, Treschan 2006, WO '907, and/or WHO Standard 2013 (obviousness);
- Prior art vasopressin labels,³³ alone or in combination with Intravenous Medications 2013, Russell 2008, Treschan 2006, WO '907,³⁴ and/or WHO Standard 2013 (obviousness);
- The HPLC claim limitations are further obvious in view of Bi 1999, Wilczynska 2002, and/or Yanagisawa 1998;
- The “discard[] a vial . . . at least 48 hours after a first puncture” limitation of the '239 patent is further obvious in view of Joint Commission 2014 Misuse of Vials and SEA 2014.

XIV. THE EXCLUDED AND WITHHELD PRIOR ART REFERENCES AND INFORMATION ARE MATERIAL TO THE PATENTABILITY OF THE ASSERTED AND/OR CHALLENGED CLAIMS

377. I have also been asked to opine on the materiality of prior art that was withheld or excluded based on statements made during prosecution by the inventors as to the patentability of the claims. In particular, I have analyzed the: April 2014 Vasostrict® Label; full Pitressin® composition properties; properties of higher pH lots of Pitressin®; and information concerning the reliability of the inventors' prosecution testing.

³³ Including American Regent Label; Fresenius Label; Pitressin® Label 2012; Pitressin® Label 2010; Cardinal Label.

³⁴ In addition to the further clinical prior art discussed by Dr. Cross, including Liverpool Hospital 2014, BH Medicine Guide, Dellinger 2013, AHFS 2011, Argenziano 1997, and other similar references discussed by Dr. Cross.

A. April 2014 Vasostrict® Label

378. It is my opinion that the April 2014 Vasostrict® Label that the applicants argued was not prior art would have been material to the patentability of the challenged claims. Furthermore, this Label is closer prior art to the challenged claims than the PPC reference, among others, cited by the examiner during prosecution following the disqualification of the April 2014 Vasostrict® Label.

1. The April 2014 Vasostrict® Label Is Material Prior Art

379. I understand from Dr. Cross's analysis that the April 2014 Vasostrict® Label discloses expressly each and every clinical element of the challenged claims of the '526, '209, '239, and '785 patents. I rely on his opinion and his conclusions regarding the clinical elements of the challenged claims and the April 2014 Vasostrict® Label.

380. In particular, from Dr. Cross's analysis, I understand that the April 2014 Vasostrict® Label discloses, among other aspects, the clinical uses recited by the claims, dilution of vasopressin formulations, and titration and tapering steps as recited by the asserted and/or challenged claims of the '526, '209, and '239 patents.

381. As set forth above, it is my opinion—consistent with the unrebutted findings of the patent examiner—that this Label disclosed each and every composition elements of the challenged claims and, to the extent it did not, rendered any remaining limitation obvious.

382. Foremost, as discussed above, the April 2014 Vasostrict® Label described a unit dosage form with 0.038 mg/mL vasopressin (20 units/mL), chlorobutanol, acetic acid for pH adjustment, and water for injection. *See, e.g.*, April 2014 Vasostrict® Label § 11. Therefore, this Label expressly taught the chemical components of the unit dosage forms recited by the challenged claims of the '526, '209, '239, and '785 patent.

383. The April 2014 Vasostrict® Label also disclosed, as previously discussed, a pH range of 3.4 to 3.6. This pH range is narrower than, and overlapping with, the recited range in the challenged claims of the '239 patent. In addition, this pH range abuts that recited in the '209 and '785 patents—3.7 to 3.9—and is just 0.2 pH units away from that recited in the '526 patent.

384. This pH range of the April 2014 Vasostrict® Label is closer to the claimed pH ranges and values than the broader range of pH 2.5 to 4.5 disclosed by PPC (cited by the examiner), among other references in the prior art. First, the range of 3.4 to 3.6 is one-seventh as broad as the range of PPC that was before the patent examiner. Second, this narrow range, as stated, is very close to what is recited by the challenged claims—much closer than much of PPC's pH range—and within the very pH region that Par now alleges is the most stable for vasopressin for optimization. *See, e.g.*, PAR-VASO-0000106 ('526 Patent Examples 9 & 10). In combination, this narrower, closer range would have served to focus a POSA's pH optimization efforts on a narrower set of pH values, namely just that of the April 2014 Vasostrict® Label and the abutting values within a limited number of pH units. When limited as such, this routine process would have become even less complicated and a POSA would easily have found any purported optimum value, including those alleged to be critical by Par and recited by the claims.

385. In addition, as discussed in detail above, the April 2014 Vasostrict® Label—as confirmed by the examiner—by virtue of expressly disclosing the same chemical components as the asserted and/or challenged claims, also inherently disclosed the impurities, stability, and degradation products limitations of the asserted and/or challenged claims. Furthermore, the data for the original Vasostrict® product disclosed in the April 2014 Vasostrict® Label, *see* § 11, described above demonstrated that this formulation actually does satisfy the various impurities, stability, and degradation products limitations, particularly in light of Par's infringement

[REDACTED]

allegations against Eagle. These specific stability and impurity results of the asserted and/or challenged claims are properties of the formulation taught by the Label and therefore were inherently disclosed in this reference.

386. Such specific stability and impurity results also confirm that the formulation disclosed in the April 2014 Vasostrict® Label comprised a plurality of peptides, another feature inherent in the disclosure of this prior art reference. Finally, these results were obtained using the recited HPLC method and thus that element is also inherently disclosed in the description of the drug product.

387. Also as described in detail above, the April 2014 Vasostrict® Label also disclosed additional formulation elements of the asserted and/or challenged claims, including a formulation that is neither lyophilized nor frozen.

388. Finally, to the extent that Par asserts that Eagle's proposed ANDA labeling instructs in accordance with the "discard" limitation for handling, the April 2014 Vasostrict® Label contained the same instruction. *See, e.g.*, § 16. Further, as found by the examiner during prosecution and discussed in detail above, it would have been obvious to refrigerate prior art vasopressin compositions like the April 2014 Vasostrict® Label prior to administration.

389. I note that Par has, in this litigation, accused Eagle's ANDA product of infringing the claims of the '526, '209, '239, and '785 patents. As set forth above, [REDACTED]

[REDACTED]

[REDACTED]

In addition, I understand that all of the instructions in Eagle's proposed label cited by Par in alleging infringement, save for a slightly different refrigerated storage instruction, are found in the April 2014 Vasostrict® Label. Therefore, to the extent that Eagle's proposed ANDA product and

labeling infringes the claims of the asserted and/or challenged patents, then the April 2014 Vasostrict® Label must anticipate those claims.

a. '239 Patent

390. The examiner found that this Label rendered all pending claims of the '239 patent invalid for anticipation—as well as obviousness—during prosecution. As I have discussed, the applicants ultimately only distinguished the remaining cited prior art, primarily PPC, based on an alleged showing of criticality of the claimed pH range of 3.5 to 4.1 over the prior art range of 2.5 to 4.5. The pH range of 3.4 to 3.6 in the Label, however, would have anticipated the broad range of the '239 patent claims as issued. This Label would therefore have anticipated the claims of the '239 patent because it discloses each and every element of each and every claim, either expressly or inherently: the chemical composition of the unit dosage form, a narrower pH, the degradation products, discard time (if Eagle's labeling is alleged to instruct infringement), and the method of treating hypotension, as set forth by Dr. Cross. Had it been properly considered before the patent office, the claims of the '239 patent would not have issued. The April 2014 Vasostrict® Label is thus material to the patentability of the '239 patent.

b. '526, '209, and '785 Patents

391. As set forth above, the April 2014 Vasostrict® Label discloses or, in the case of refrigeration, renders obvious, the limitations of the '526, '209, and '785 patents, including with respect to the recited chemical composition of the unit dosage form, degradation and impurity levels, storage conditions, HPLC method, and the method of treating hypotension, as set forth by Dr. Cross.

392. Despite the different pH limitations of the '526, '209, and '785 patents, the April 2014 Vasostrict® Label and its pH range of 3.4 to 3.6 still render the asserted claims of these patents obvious. Given that the range of 3.4 to 3.6 is abutting (for the '209 and '785 patents) or

otherwise very close ('526 patent) to the recited pH, a POSA would have expected these compositions all to have similar properties. Although pH-dependent stability could change over even narrow ranges, the differences are typically small when looking at such ranges. Based on both my own review and Dr. Chyall's analysis, the basic stability studies conducted by Par confirm that formulations pH 3.4 to 3.6 do indeed behave similarly to the abutting recited values.

393. Given that these pH values result in similar stability, the applicants would not have been able to show criticality over the pH range of the April 2014 Vasostrict® Label. I understand from Dr. Chyall's opinion, based on his analysis of the pH data before the patent office and the experiments used to generate those data, that there is no indication that the particular claimed values led to any unexpected increase in stability relative to the pH range of the April Vasostrict® 2014 Label.

394. I also understand from Dr. Chyall's analysis, and agree, that the testing presented by the applicants during prosecution could not have shown criticality over the formulation set forth in the April 2014 Vasostrict® Label. That Label described a complete composition that had been developed by Par, with a shelf life of 12 months for which Par had extensive stability data. Showing criticality over that formulation would have required testing the claimed formulations against that prior art formulation, when instead the inventors tested a different formulation comprising just acetate buffer (which was not a component of the formulation in the April 2014 Vasostrict® Label) and vasopressin. It also would have required testing for the full shelf life set forth in the label and comparison with Par's own stability data, rather than just four weeks with contrived data.

395. Furthermore, consistent with my analysis set forth above for obviousness, a POSA would have found the optimization of pH around the range of the April 2014 Vasostrict® Label to

be routine. pH optimization of a peptide formulation is a routine process in the field of pharmaceutical dosage form design and development that is fundamental to the entire endeavor. When formulating vasopressin, a POSA would have looked to this range—the pH value used for an FDA-reviewed and FDA-approved drug product—for guidance and focused on testing pH values within and surrounding this range. These standard analyses would have rapidly revealed the optimum range or value—if any—and led a POSA to use the recited values, to the extent they truly are more stable.

396. Beyond the lack of data establishing criticality over this pH range from the April 2014 Vasostrict® Label, there is no indication that there is any benefit to the formulations and pH values of the asserted claims of the '526, '209, and '785 patents. Though the inventors claimed in declarations to the patent office that the formulations of these patents had lower impurity values relative to formulations with different pHs within the 2.5-4.5 range including those with pHs of 3.4-3.6, they never compared the data obtained for the claimed pH values with stability data they had for the formulation described in the April 2014 Vasostrict® Label including that submitted with Par's NDA, much less showed any numerical increase in assay or decrease in impurities, and still less any clinical or safety benefit to such a result (to the extent there were actually lowered impurities). *See, e.g.,* Kannan Dep. 187:22–188:22; Vandse Dep. 254:16–22; Sanghvi Dep. 146:21–147:5, 148:14–149:8, 150:13–18, 151:3–22.

397. Given that the April 2014 Vasostrict® Label describes an actual formulation of vasopressin that was offered for sale by Par, there are also a number of FDA findings and representations that refute any alleged criticality of the asserted claims relative to the April 2014 Vasostrict® Label. When seeking approval for NDA 204485 on the original Vasostrict® product, Par represented to the FDA that:

[REDACTED]

pH is a critical parameter in the manufacture of Pitressin®. The pH of the product solution, in regards to creating and formulating with the highly water-soluble acid-salt form of the drug substance, influences the performance of the drug product. At a pH range of 3.4 - 3.6, the vasopressin acid salt is relatively stable in water. At pHs below 3.4 and above 3.6, degradation of vasopressin accelerates, with the reaction increasing as the pH deviates further from the formulated range.

PAR-VASO_0072478. This means that the prior art Vasostrict® formulation described in the April 2014 Vasostrict® Label was already optimized for the stability of vasopressin. And though Par removed the original Vasostrict® product from the market with the launch of the reformulated Vasostrict® product it now contends is covered by the asserted claims of the '526, '209, and '785 patents, the FDA has expressly “determined that the original formulation of Vasostrict, 20 units per mL, was not discontinued from sale for reasons of safety or effectiveness.” *E.g.*, <https://www.regulations.gov/contentStreamer?documentId=FDA-2017-P-1096-0004&attachmentNumber=1&contentType=pdf>. Like the inventors, the FDA could also not determine any detrimental property of original Vasostrict® or material benefit in safety or effectiveness for the formulations of the asserted claims. Indeed, Par was unable to secure any shelf life benefit by reformulating its Vasostrict® product, or beneficial change in impurities specifications; the shelf lives and total impurities specifications of the original and reformulated Vasostrict® products are identical. *See, e.g.*, PAR-VASO_0093671; [Vandse Dep. Tr. 235:7–237:12; Kannan Dep. Tr. 176:11–17, 177:14–20, 305:8–306:10.]

398. In fact, even before the testing it submitted to the Patent Office, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

399.

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

403. Because the elements of the asserted claims of the '526, '209, and '785 patents are expressly or inherently disclosed in this Label, save for pH, the Label would have rendered the claims of the '526, '209, and '785 patents invalid as obvious had this reference been before the patent office, particularly because the pH values of these claims are not critical over the April 2014 Vasostrict® Label. The April 2014 Vasostrict® Label is therefore material to the patentability of the '526, '209, and '785 patents.

2. The April 2014 Vasostrict® Label Is the Closest Prior Art to the Asserted and/or Challenged Claims

404. In addition, it is my opinion that the April 2014 Vasostrict® Label is the closest prior art to the challenged claims of the '526, '209, '239, and '785 patents.

405. Unlike the PPC reference, among others, cited by the examiner, the April 2014 Vasostrict® Label discloses each and every limitation of the challenged claims of the '239 patent in a single reference and therefore anticipates those claims. Regarding pH, there would have been no need to consider whether the claims of the '239 patent recite a pH range that is critical because the April 2014 Vasostrict® Label teaches an anticipating range.

406. For the '526, '209, and '785 patents, the April 2014 Vasostrict® Label discloses a pH range that abuts or is much closer to the claimed pH ranges than the PPC range of 2.5 to 4.5. Indeed, as set forth above, the patents themselves reproduce material from the April 2014 Vasostrict® Label as part of their disclosures, including the particular pH range of that

formulation. At most, the lower end of the April 2014 Vasostrict® Label is just 0.4 pH units away from the claims of the '526 patent, while the PPC reference included pH values some 1.3 units away. Thus, the April 2014 Vasostrict® Label would have focused a POSA more specifically on the specific claimed values for optimization and is therefore a closer prior art reference.

407. In addition, the PPC reference did not disclose the clinical elements of the claims because it carries different indications and instructions for use. The April 2014 Vasostrict® Label, however, as set forth in Dr. Cross's report, disclosed each of the clinical elements exactly. To the extent met by Eagle's ANDA product labeling, the April 2014 Vasostrict® Label also disclosed additional handling steps, like the discard limitation, that are not in PPC.

408. Finally, although the examiner found that another prior art reference, Treschan, taught many of the clinical elements, they needed to be combined with other prior art to meet the claims, including the clinical elements. As stated in Dr. Cross's report, the April 2014 Vasostrict® Label disclosed those clinical elements essentially verbatim. In addition, the disclosures of the additional dilution references—Russell, Young, and Buck—cited for those method steps were also obviated by the disclosure of the April 2014 Vasostrict® Label, as noted by Dr. Cross. And unlike those references, the April 2014 Vasostrict® Label taught the specific components for the composition of vasopressin, not just the method of using it.

B. Pitressin® Properties

409. I understand that key properties of Pitressin®, including its target pH as well as the pH of many specific lots with values above that target range, were not disclosed to the patent office during prosecution of the challenged patents. This information is material to patentability and is closer prior art than the PPC reference over which the inventors argued criticality before the patent office.



Dated: November 15, 2019

A handwritten signature in cursive script that reads "Kinam Park".

Kinam Park, Ph.D.

EXHIBIT 4

REDACTED

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**


<p>PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC and ENDO PAR INNOVATION COMPANY, LLC,</p> <p>Plaintiffs,</p> <p>v.</p> <p>EAGLE PHARMACEUTICALS INC.,</p> <p>Defendant.</p>	<p>C.A. No. 18-cv-823-CFC</p> <p></p>
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EXHIBIT 15.1.3

**PLAINTIFFS' REPLY IN SUPPORT OF ITS MOTION IN LIMINE #1
TO STRIKE AND PRECLUDE ANY OPINION AND TESTIMONY
REGARDING MATTER NEWLY RAISED IN
DR. PARK'S REPLY EXPERT REPORT**

Eagle offers no explanation for not timely disclosing LT-4487. Instead, it paints a misleading picture about Dr. Kirsch's rebuttal report and Dr. Park's new opinions. Kirsch nowhere opined that "the prior art showed pH was unimportant to vasopressin stability." *See* Mot.Opp. at 1 (lacking citation). And, Eagle knew months before opening reports that Par contended "prior art references would have directed a POSA away from the claimed [pH] values" and "Par discovered the claimed pH value, through diligent work, despite the absence of any teaching toward it." Ex. A (Contentions) at 21-22, 29, 33, 38, 42. If LT-4487 is "important to Eagle," it should have been timely disclosed. Park's deposition testimony about LT-4487, which is fraught with speculation, does not cure the prejudice of Par being deprived of appropriate fact discovery. LT-4487 "was not vetted through discovery" and should be excluded. *Cradle IP, LLC v. Texas Instruments, Inc.*, 5 F. Supp. 3d 626, 639-40 (D. Del. 2013).

As for Park's new opinions on the declarations, that he opined on the alleged materiality of the label in his opening report is irrelevant. He made no mention of the declarations he first addressed in his reply. His new opinions are therefore not "reasonable elaboration" of his opening opinions. They are improper. *See Waddington N. Am., Inc. v. Sabert Corp.*, No. 09-4883 (GEB), 2011 WL 1098996, at *8 (D.N.J. Mar. 22, 2011) (excluding expert declaration, noting "it is

unnecessary if it is a mere elaboration and is improper if it expresses new opinions”).

Dated: May 11, 2020

Respectfully submitted,

FARNAN LLP

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Par Innovation Company, LLC*

CERTIFICATION OF COMPLIANCE

The foregoing document complies with the type-volume limitation of this Court's March 2, 2020 form Scheduling Order For All Cases where Infringement is Alleged. The text of this brief, including footnotes, was prepared in Times New Roman, 14 point. According to the word processing system used to prepare it, the brief contains 250 words, excluding the case caption, signature block, table of contents and table of authorities.

/s/ Brian E. Farnan

Brian E. Farnan (Bar No. 4089)

Dated: May 11, 2020

EXHIBIT A

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

PAR PHARMACEUTICAL, INC., PAR
STERILE PRODUCTS, LLC, and ENDO
PAR INNOVATION COMPANY, LLC,

Plaintiffs,

V.

EAGLE PHARMACEUTICALS INC.,

Defendant.

Case No. C.A. No. 18-823-CFC

**PLAINTIFFS PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, AND
ENDO PAR INNOVATION COMPANY, LLC’S RESPONSE TO DEFENDANT EAGLE
PHARMACEUTICALS INC.’S INVALIDITY CONTENTIONS**

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the use of a preservative to extend shelf-life generally, and does not describe a process for formulating vasopressin or storing it in a stable medium with 0 – 2% degradation products.

Accordingly, Eagle has failed to demonstrate that the cited prior art renders this limitation obvious.

iii. *The unit dosage form has a pH of 3.5 to 4.1*

None of the prior art cited by Eagle expressly discloses this limitation. Nor does Eagle cite any evidence that the pH of Pitressin was known prior to the time of the claimed inventions of the patents-in-suit. Eagle cites disclosures in the FDA Biopharmaceutics Review regarding the pH of Pitressin, but as noted above, Eagle fails to show that that document qualifies as prior art and does not cite any evidence that the pH of Pitressin was known prior to the time of the claimed inventions. Without demonstrating that the pH of Pitressin was known to POSAs, Eagle cannot demonstrate that it would have been obvious to modify or combine the prior art to arrive at the pH range recited in these claims.

Eagle argues that the Vasopressin Labels and PPC 2009 disclose pH ranges of 2.5 – 4.5 that overlap with the range recited in this limitation. There is nothing in these references that would have directed a POSA towards the claimed pH values. Other prior art, however, would have directed a POSA away from the claimed values. For example, the Bi 2000 reference reported optimal stability of 3.35 for vasopressin. Bi 2000 at 90 (“Fig. 2 indicates that AVP is most stable at pH 3.35 among pH values tested and its degradation rate is highly pH – dependent.”). And Connors taught that the “[m]aximal stability [of vasopressin] is seen at pH 3.” Connors at 787.

Additionally, testing performed by Par, including the work reflected in the prosecution histories, the patent specifications, and other development documentation, show the criticality of pH to the stability of vasopressin and the levels of impurities. *See, e.g.*, ’526 patent at Examples

9, 10 and Figs. 11 – 18; PAR-VASO_0002304 – 317; PAR-VASO_0002580 – 590; PAR-VASO_0004903 – 910; PAR-VASO_0008804 – 824; PAR-VASO_0093612 – 671; PAR-VASO_0226936 – 7034. Eagle seeks to rebut this evidence by arguing that there was no teaching away, but as noted above, to the extent it was applicable, prior art references would have directed a POSA away from the claimed values. Par also disputes Eagle's criticisms of the reliability of its test results.

Eagle's citation of general references purporting to show that optimizing stability is desirable and that pH is one factor that may affect stability is similarly inadequate to render this limitation obvious. Eagle uses impermissible hindsight reasoning to reconstruct the claimed inventions without any guidance from the art as to how or why to do so. For example, Eagle alleges that a POSA would have optimized the stability of prior art vasopressin formulations, but Eagle points to no evidence showing that the stability of those formulations was a concern or known to be in need of improvement. Moreover, in view of the unpredictability of the art with respect to peptide formulations, the vast array of options for potentially improving stability, and the evidence that the prior art pointed away from the particular solutions claimed by the inventors here, among other things, Eagle has failed to show by clear and convincing evidence that the claimed pH values would not have been obvious in view of the prior art it cites.

iv. Diluting the unit dosage form in a diluent to provide a concentration from about 0.1 units/mL to about 1 unit/mL of vasopressin or the pharmaceutically – acceptable salt thereof

The cited references do not disclose or render obvious the unit dosage form as claimed.

v. Administering the diluted unit dosage form to the human by intravenous administration

The cited references do not disclose or render obvious the unit dosage form as claimed.

the asserted claims” (*ActiveVideo Networks*, 694 F.3d at 1327); why the combination allegedly “yield[s] a predictable result” (*KSR*, 550 U.S. at 416), or “why a person of skill in the art would have combined the elements from specific references *in the way the claimed invention does*” (*ActiveVideo Networks*, 694 F.3d at 1328 (emphasis in original) (citing *KSR*, 550 U.S. at 418)).

In fact, other than Avanti 2012 and Chang (which is not asserted as prior art), the only specific evidence to which Eagle cites is Par’s own internal research documents and PTO submissions. This is improper and falls far short of meeting Eagle’s burden.

i. pH limitation

The reasons set forth above as to why the pH range of 3.5 – 4.1 claimed in the ’239 patent is not obvious in view of the prior art apply with even more force here where the claimed pH value is a narrower subset of that range (3.8). The testing performed by Par, including the work reflected in the prosecution histories, the patent specifications, and other development documentation, show the criticality of the recited pH value to the stability of vasopressin and the levels of impurities. *See, e.g.*, ’526 patent at Examples 9, 10 and Figs. 11 – 18; PAR-VASO_0002304 – 317; PAR-VASO_0002580 – 590; PAR-VASO_0004903 – 910; PAR-VASO_0008804 – 824; PAR-VASO_0093612 – 671; PAR-VASO_0226936 – 7034; PAR-VASO_003050563 – 582. Par discovered the claimed pH value, through diligent work, despite the absence of any teaching toward it. Eagle’s *ipse dixit* statement that “a single point *and* a broad range cannot simultaneously maximize the same property,” Invalidity Contentions at 65, misses the point and reflects a misunderstanding of the law—the fact that a range of values may be non-obvious and critical to a claimed invention does not mean that any individual point within that range cannot also be claimed as part of a non-obvious invention. Accordingly, the prior art does not render this limitation obvious.

modify the specified prior art combination as to allegedly render any of the asserted claims of the '526 patent invalid as obvious under 35 U.S.C. § 103.

Par has used its best efforts to understand Eagle's invalidity allegations for the asserted claims of the '526 patent in order to respond to the validity contentions. Par further refers to and incorporates herein its responses to the summaries of the cited prior art set forth above, and further reserves the right to supplement its responses based on any future positions taken by Eagle in this matter.

2. Differences between prior art and claims 1 – 20 of the '526 patent

a. Claim 1

Par disputes that Eagle has provided clear and convincing evidence that the proposed art identified by Eagle discloses the limitations of claim 1 of the '526 patent for at least the same reasons as for claim 1 of the '239 patent and claim 1 of the '478 patent noted above. Eagle has failed to show how any “specific references could be combined, which combination(s) of elements in specific references would yield a predictable result, [and] how any specific combination would operate or read on the asserted claims” (*ActiveVideo Networks*, 694 F.3d at 1327); why the combination allegedly “yield[s] a predictable result” (*KSR*, 550 U.S. at 416), or “why a person of skill in the art would have combined the elements from specific references *in the way the claimed invention does*” (*ActiveVideo Networks*, 694 F.3d at 1328 (emphasis in original) (citing *KSR*, 550 U.S. at 418)).

i. pH limitation

Eagle raises and relies upon the same arguments with respect to this limitation as it did with respect to the pH limitation in the '478 patent, and its contentions are deficient for the same reasons as set forth above with respect thereto.

i. pH limitation

The reasons set forth above as to why the pH range of 3.5 – 4.1 claimed in the '239 patent is not obvious in view of the prior art apply with even more force here where the claimed pH value is a narrower subset of that range (3.7 – 3.9). The testing performed by Par, including the work reflected in the prosecution histories, the patent specifications, and other development documentation, show the criticality of the recited pH value to the stability of vasopressin and the levels of impurities. *See, e.g.*, '526 patent at Examples 9, 10 and Figs. 11 – 18; PAR-VASO_0002304 – 317; PAR-VASO_0002580 – 590; PAR-VASO_0004903 – 910; PAR-VASO_0008804 – 824; PAR-VASO_0093612 – 671; PAR-VASO_0226936 – 7034; PAR-VASO_003050563 – 582. Par discovered the claimed pH range, through diligent work, despite the absence of any teaching toward it. Eagle's *ipse dixit* statement that "[d]ifferent pH targets . . . cannot simultaneously be critical to optimizing the same property," Invalidity Contentions at 85, misses the point and reflects a misunderstanding of the law—the fact that a range of values may be non-obvious and critical to a claimed invention does not mean that a narrower subset within that range cannot also be claimed as part of a non-obvious invention. Accordingly, the prior art does not render this limitation obvious.

ii. Impurities

As Eagle implicitly concedes, none of the cited prior art expressly discloses this limitation. Nor does Eagle cite any evidence that any POSA was actually in possession of this limitation prior to the time of the claimed inventions. Instead, Eagle raises and relies upon the same arguments with respect to this limitation as it did with respect to the 0 – 2% vasopressin degradation products limitation of claim 1 of the '239 patent and claims 2 – 4 of the '239 patent, and its contentions are deficient for the same reasons as set forth above with respect thereto. Eagle's assertions that this limitation would have been obvious is based on an unsupported and

modify the specified prior art combination as to allegedly render any of the asserted claims of the '209 patent invalid as obvious under 35 U.S.C. § 103.

Par has used its best efforts to understand Eagle's invalidity allegations for the asserted claims of the '785 patent in order to respond to the validity contentions. Par further refers to and incorporates herein its responses to the summaries of the cited prior art set forth above, and further reserves the right to supplement its responses based on any future positions taken by Eagle in this matter.

2. Differences between prior art and claims 1 – 9 & 11 of the '785 patent

a. Claim 1

Par disputes that Eagle has provided clear and convincing evidence that the proposed art identified by Eagle discloses at least the limitations of claim 1 of the '785 patent for at least the same reasons as for each claim 1 of the patents noted above. Eagle has failed to show how any “specific references could be combined, which combination(s) of elements in specific references would yield a predictable result, [and] how any specific combination would operate or read on the asserted claims” (*ActiveVideo Networks*, 694 F.3d at 1327); why the combination allegedly “yield[s] a predictable result” (*KSR*, 550 U.S. at 416), or “why a person of skill in the art would have combined the elements from specific references *in the way the claimed invention does*” (*ActiveVideo Networks*, 694 F.3d at 1328 (emphasis in original) (citing *KSR*, 550 U.S. at 418)).

i. pH limitation

Eagle raises and relies upon the same arguments with respect to this limitation as it did with respect to the pH limitations in the '209 patent, and its contentions are deficient for the same reasons as set forth above with respect thereto.

3. The asserted claims are sufficiently enabled

Eagle's arguments for indefiniteness repeat arguments that it made for indefiniteness of the other patents addressed above, and those arguments fail for the reasons noted above with respect to those patents.

XII. OBJECTIVE INDICIA OF NONOBVIOUSNESS

As noted above, Eagle has failed to meet its prima facie case of obviousness; therefore, Par need not assert any objective indicia of nonobviousness in support of its position.

XIII. CONCLUSION

Based upon the information available to Par, Eagle has failed to prove by clear and convincing evidence that the asserted claims of the '239, '478, '526, '209, '785, and '223 patents are invalid at least on the grounds set forth above. Discovery and Par's investigation is ongoing, and Par reserves the right to modify and/or supplement its validity contentions.

Dated: August 23, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Brian E. Farnan, hereby certify that on August 23, 2019, a copy of Plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC's Response to Defendant Eagle Pharmaceuticals Inc.'s Invalidity Contentions was served on the following as indicated:

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CONFIDENTIAL

EXHIBIT 15.2

PAR'S MOTION *IN LIMINE* NO. 2

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**


<p>PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC and ENDO PAR INNOVATION COMPANY, LLC,</p> <p>Plaintiffs,</p> <p>v.</p> <p>EAGLE PHARMACEUTICALS INC.,</p> <p>Defendant.</p>	<p>C.A. No. 18-cv-823-CFC</p> <p></p>
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EXHIBIT 15.2.1

**PLAINTIFFS' MOTION IN LIMINE # 2 TO PRECLUDE STATE
OF MIND TESTIMONY BY EAGLE'S EXPERTS**

In their reports, Eagle's experts make numerous assertions regarding intent, motive, and state of mind which should be precluded. Courts in this District routinely preclude expert testimony regarding "intent, motive, or state of mind, or evidence by which such state of mind may be inferred." *Oxford Gene Tech. Ltd. v. Mergen Ltd.*, 345 F. Supp. 2d 431, 443 (D. Del. 2004); *see also AstraZeneca LP v. Tap Pharm. Prods., Inc.*, 444 F. Supp. 2d 278, 293-94 (D. Del. 2006); *Liqwd, Inc. v. L'Oréal USA, Inc.*, No. 17-14-JFB-SRF, 2019 WL 8014103, at *5 (D. Del. June 25, 2019). This is because such opinions "have no basis in any relevant body of knowledge or expertise." *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (D. Del. 2004). Such testimony is harmful and prejudicial because it allows unqualified experts "improperly to assume the role of advocates for the [party]'s case by arguing as to the intent or motives" underlying a particular action. *Id.*

For example, in Dr. Chyall's reports, he opines that the inventors and Par "were driven to selectively produce and withhold information in order to support their criticality allegations." Ex. B (Chyall Reply Report) ¶ 90; *see also* Ex. A (Chyall Opening Report) ¶¶ 84 ("[T]he data provided to the examiner were improperly presented and skewed to mislead the examiner . . ."), 141. This is legal argument masquerading as expert opinion. Dr. Chyall is simply not qualified to testify regarding why the inventors or Par submitted declarations. *See* Ex. C (Chyall C.V.). These opinions should be stricken and all of Eagle's experts should

be precluded from testifying at trial on the subject of inventor and corporate intent or state of mind.

In addition, Eagle's experts should not be permitted to opine about the patent examiner's state of mind, including what the examiner would have done given different information. Experts in patent cases are not experts "in the field of retroactive mind reading of the thoughts of patent examiners" and thus may not opine or testify "as to the thought processes of an examiner who was provided with different information." *See Barry v. Medtronic, Inc.*, No. 1:14-cv-104, 2016 WL 7665782, at *2 (E.D. Tex. July 19, 2016); *Abbott Biotech. Ltd. v. Cenocor Ortho Biotech, Inc.*, No. 09-40089-FDS, 2014 WL 7330777, at *8 (D. Mass. Dec. 19, 2014) (holding that an expert "may not speculate as to what the examiner did or did not think, or how different information would have impacted the examiner's opinions or thoughts...."); *accord The Medicines Co. v. Mylan Inc.*, No. 11-cv-1285, 2014 WL 1516599, at *4 (N.D. Ill. Apr. 17, 2014); *Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc.*, No. C 92-20643 RMW, 1995 WL 261407, at *3 (N.D. Cal. Apr. 25, 1995).

Here, Eagle's experts repeatedly opine regarding what the Examiner would have done if provided with different information—*e.g.*, Dr. Chyall opines that "had the Examiner relied on the April 2014 Vasostrict Label as prior art, she would not have permitted the issuance of the claims of the patents-in-suit." Ex. A ¶ 132; *see*

also, e.g., Ex. D (Cross Report) ¶ 247; Ex. E (Park Opening Report) ¶ 390.

Similarly, Dr. Chyall's opinions regarding what the Examiner understood or relied on should be similarly excluded. *See, e.g.*, Ex. B ¶ 96 (“[I]t is evident that the Examiner relied on the inventors to accurately and comprehensively disclose the variability present in the data so that she could come to a reliable conclusion.”).

The Court should exclude any such opinions or testimony regarding what the Examiner thought or would or would not have done under different circumstances, or what the Examiner's thought processes were. Such speculative statements are irrelevant and outside the province of scientific expert testimony. Neither Dr. Park nor Dr. Chyall is an expert in patent law or patent prosecution procedure. *See* Ex. F (Chyall Dep.) 38:10-20; Ex. E, Ex. C.

Accordingly, Par respectfully requests that the Court strike all state of mind opinions from the below paragraphs and preclude Eagle's experts from testifying regarding state of mind—including without limitation inventor intent and examiner state of mind—at trial:

- Cross ¶¶ 47, 243-253;
- Park Opening Section XIV, particularly ¶¶ 390, 416, 426, 432;
- Ex. G, Park Reply ¶¶ 25, 37, 53; Section VI, particularly ¶ 156;
- Chyall Opening ¶¶ 9, 83-84, 90, 102, 111-114, 118, 121, 124-125, 127, 130-132, 136, 141-146, 149, 155-156, 170, 177, 186, 188, 194-195; and
- Chyall Reply ¶¶ 12, 19, 21, 60, 90, 96, 120.

Dated: May 11, 2020

Respectfully submitted,

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CERTIFICATION OF COMPLIANCE

The foregoing document complies with the type-volume limitation of this Court's March 2, 2020 form Scheduling Order For All Cases where Infringement is Alleged. The text of this brief, including footnotes, was prepared in Times New Roman, 14 point. According to the word processing system used to prepare it, the brief contains 750 words, excluding the case caption, signature block, table of contents and table of authorities.

/s/ Brian E. Farnan
Brian E. Farnan (Bar No. 4089)

Dated: May 11, 2020

EXHIBIT A

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

PAR PHARMACEUTICAL, INC., PAR
STERILE PRODUCTS, LLC, and ENDO
PAR INNOVATION COMPANY, LLC,
Plaintiffs,

v.

EAGLE PHARMACEUTICALS INC.,
Defendant.

C.A. No. 18-00823-CFC

OPENING EXPERT REPORT OF LEONARD J. CHYALL, PH.D.

and ranges of the asserted claims (*i.e.*, 3.5–4.1, 3.7–3.9, and 3.8) are critical over PPC’s pH of 2.5–4.5.

9. Furthermore, I have been asked to provide my opinion as to whether the data presented by the inventors during prosecution of the patents-in-suit would have been sufficient to show criticality over the formulation described in an April 2014 label for the original formulation of Par’s Vasostrict product, which set forth a pH range of 3.4–3.6. As I explain below, it is my opinion that they would not have been. Had the April 2014 label been relied upon by the Examiner as prior art, the inventors could not have made the criticality claims they did based on the submitted data.

10. Relatedly, as I describe in the background section of this report, I understand that Pitressin and the original Vasostrict formulation are prior art vasopressin formulations that were sold prior to the earliest effective filing dates of the patents-in-suit. I understand that these products were both sold with an initial pH range of 3.4–3.6 before the earliest filing date of the patents-in-suit. For the reasons discussed below, it is my opinion that the data and information set forth in the Kannan Declaration do not demonstrate that the claimed pH and ranges of the asserted claims (*i.e.*, 3.5–4.1, 3.7–3.9, and 3.8) are critical over Pitressin and Vasostrict, with their initial pH range of 3.4–3.6.

11. Finally, I have been asked to provide my opinion regarding whether certain information that the inventors withheld from the Examiner during prosecution relating to the testing and resulting data they submitted in support of their criticality assertions, including certain normalized data and results of a separate pH optimization study, would have been material to the prosecution of the patents-in-suit. For the reasons discussed below, it is my opinion that they would have been.

batch record, shows that American Regent's vasopressin product was manufactured to have a target pH of 3.8. *See* AR3-VASO-0000001-22. Each milliliter of American Regent's product contained 20 I.U. (*i.e.*, units) of Vasopressin, USP; 9 mg of Sodium Chloride, USP; and 5 mg of chlorobutanol, NF as an antimicrobial agent. The sale of American Regent's vasopressin product to the public is reflected in its sales record. *See* AR3-VASO-0000009.

VI. SUMMARY OF OPINIONS

83. In my opinion, the data and information set forth in the Kannan Declaration—even if assumed to be reliable and correct, and even after setting aside the variability inherent in the data—does not demonstrate that the pH values and ranges of the asserted claims (*i.e.*, 3.5–4.1, 3.7–3.9, and 3.8) are critical for stability of vasopressin formulations as compared to the April 2014 Vasostrict Label, the original Vasostrict formulation, or Pitressin. Thus, had the examiner relied on one or more of those prior art references or products, the inventors would not have been able to secure the issuance of the patents-in-suit.

84. It is further my opinion that the inventors withheld critical information from the examiner that would have been directly material to assessing their claims of criticality of the claimed pH and ranges of the patents-in-suit (*i.e.*, 3.5–4.1, 3.7–3.9, and 3.8). In fact, as I detail below, the inventors selectively produced and withheld relevant information such that the data provided to the examiner were improperly presented and skewed to mislead the examiner to believe that the claimed claimed pH and ranges could be genuinely distinguished from the prior art. In my opinion, there is no rationale or scientific basis for the inventors' selective production and presentation of the data to the patent office.

85. It is further my opinion that the inventors cannot establish the criticality of the claimed pH and ranges in any event because there were prior art vasopressin formulations available

April 2014 Vasostrict Label disclosed each and every limitation of all pending claims, and therefore anticipated them. PAR-VASO-0006453 at 8325–329, 8349-356. The examiner, however, withdrew her rejection over the April 2014 Vasostrict Label, based on the Kannan and Bonomi-Huvala declarations, which alleged that the information set forth in the April 2014 Vasostrict Label originated from the named inventors, Matthew Kenney and Vinayagam Kannan.

89. In my view, the fact that the examiner found that the April 2014 Vasostrict Label teaches every limitation of all pending claims is itself clear evidence that the Label was material prior art. Furthermore, it is my understanding that Drs. Kinam Park and Carmen Cross have concluded that the April 2014 Vasostrict Label discloses each and every limitation of the '239 patent claims as issued, either expressly or inherently.

90. I understand one cannot overcome an anticipation rejection by demonstrating criticality. Because the pending claims of the '877 Application were rejected on the basis of anticipation, the inventors could not have relied on alleged criticality to overcome the rejection. Nor could they have relied on criticality to overcome an objection of the final claims as anticipated by the April 2014 Vasostrict Label. Thus, in my opinion, the claims of the '239 patent would not have issued, had the examiner relied on the April 2014 Vasostrict Label as prior art.

91. Accordingly, it is my opinion that the April 2014 Vasostrict Label satisfies the but-for materiality standard for the '239 patent.

92. My review of the April 2014 Vasostrict Label and the issued claims of the '239 patent confirms that the issued claims of the '239 patent would have been anticipated (which would preclude criticality). The claims of the '239 patent recite a method of increasing blood pressure in a human in need thereof by administering vasopressin. For example, Claim 1 recites as follows:

1. A method of increasing blood pressure in a human in need thereof, the method comprising:

b. The inventors could not have shown criticality over the April 2014 Vasostrict Label for the claims of the '526, '209, and '785 patents

101. The '526, '209, and '785 patents are each continuations-in-part of the '239 patent, and as with the '239 patent, both Vinayagam Kannan and Matthew Kenney are named as inventors. Further, the same examiner who reviewed the '239 patent (Christina Bradley) was the examiner of record during prosecution of the '526, '209, and '785 patents.

102. The applications for the '526, '209, and '785 patents were each filed after the examiner had disqualified the April 2014 Vasostrict Label during prosecution of the '239 patent. As set forth below, had the April 2014 Vasostrict Label been available as prior art for the examiner, it is my opinion that the inventors could not have shown criticality of the claims of the '526, '209, and '785 patents.

103. Importantly, the claims of the '526, '209, and '785 patents are highly similar to the claims of the '239 patent. The main difference between the '239 patent claims and those of the '526, '209, and '785 patents is that the latter three patents have narrower claimed pH ranges or value (3.8 for the '526 patent and 3.7–3.9 for the '209 and '785 patents). For example, the '526 patent, like the '239 patent, claims administering a vasopressin formulation comprising: (1) about 0.01 to about 0.07 mg/mL vasopressin; (2) acetic acid; and (3) water. *See, e.g., '526 patent at claim 1.* The '526 patent recites the same rate of administration as the '239 patent: 0.01 to 0.1 units of vasopressin per minute. *See, e.g., id.*

104. Both the '209 and '785 patents require a vasopressin formulation comprising about 0.01 to about 0.07 mg/mL vasopressin. *See, e.g., '209 patent at claim 1; '785 patent at claim 1.* The '209 patent also recites the same rate of administration as the '239 patent: 0.01 to 0.1 units of vasopressin per minute. *See, e.g., id.*

108. I understand that Par has not yet contended that there is a material difference between [REDACTED]

109. I also am aware that Par has alleged that Eagle's ANDA product and its proposed label meet each and every limitation of the asserted claims of the '526, '209 and '785 patents, and therefore infringe the asserted claims. [REDACTED]

[REDACTED] it must follow then that the original Vasostrict product and the April 2014 Vasostrict Label also meet each and every limitation of the asserted claims of the '526, '209 and '785 patents, thereby anticipating the asserted claims.

110. Thus, Par's assertion of infringement in this action establishes that the April 2014 Vasostrict Label is material prior art to the asserted claims of the '526, '209 and '785 patents. Further, because under Par's allegation of infringement, the April 2014 Vasostrict Label (and the original Vasostrict, which is described therein) would anticipate the asserted claims of the '526, '209 and '785 patents, any allegations of criticality would be irrelevant. The inventors could not have secured the issuance of those claims, regardless of the substance of their criticality allegations.

ii. The data set forth in the Kannan declaration could not have demonstrated criticality over the April 2014 Vasostrict Label

111. The data provided in the declarations submitted during the prosecution of the patents-in-suit (*e.g.*, the Kannan Declaration & Vandse Declaration) do not support the inventors' argument that the claimed pH and ranges (*i.e.*, 3.7–3.9, and 3.8) of the '526, '209 and '785 patents are critical. In this section, I set aside the design flaws, errors in analysis, and the general unreliability of the data set forth in the these declarations, and provide my views on whether the

[REDACTED]

data from those declarations could establish criticality of the claimed pH and ranges, had the April 2014 Vasostrict Label been available as prior art to the examiner of the patents-in-suit. My view is, even making the assumption that all data recited in the declarations are reliable (an assumption with which I disagree), the data does not demonstrate the criticality of the claimed pH and pH ranges (*i.e.*, 3.7–3.9, and 3.8) over the April 2014 Vasostrict Label.

112. I understand that in seeking to establish criticality of a claimed element over the prior art, it is insufficient to demonstrate a difference in mere degree, rather than in kind. It is my opinion that, if the April 2014 Vasostrict Label were relied on by the examiner as prior art, the inventors could not have shown a difference in kind for the pH ranges required in the claims of the '526, '209 and '785 patents over the April 2014 Vasostrict Label (or Vasostrict, which is described in the label). A close inspection of the data set forth in the declarations shows that the stability of vasopressin formulations stored at the claimed pH and ranges (*i.e.*, 3.7–3.9, and 3.8) is effectively indistinguishable from those formulations with the pH of 3.4–3.6, a range expressly disclosed in the April 2014 Label.

113. During prosecution of each of the '526, '209, and '785 patents, the examiner rejected the pending claims as obvious in view of PPC, which discloses a pH of 2.5 to 4.5 *See* PAR-VASO-0002629 at 4766–68 ('526 patent); PAR-VASO-0005400 at 5732–34 ('209 patent); PAR-VASO-0009650 ('785 patent). The examiner withdrew her rejections based on the data submitted in the Kannan Declaration (and supporting Vandse declarations, which contain duplicative data), which I understand was included in Example 10 of each of the '209 and '785 patents. PAR-VASO-0002629 at 5382 ('526 patent); PAR-VASO-0005400 at 6436 ('209 patent); PAR-VASO-0009319 at 10349 ('785 patent); *see also* PAR-VASO-0005400 at 5816–517 (relying on data included in Example 10 and Figures 15–18 of the '209 patent specification to support the

alleged criticality of a pH of 3.7–3.9); PAR-VASO-0009319 at 9721–722 (relying on same data from '785 patent specification) As set forth herein, had the examiner relied on the April 2014 Vasostrict Label, including its disclosure of vasopressin with pH of 3.4 to 3.6, the inventors could not have established criticality.

a) The inventors admitted during prosecution that the pH range disclosed in the April 2014 Vasostrict Label is stable

114. It is my opinion that the examiner would not have found the claimed pH and ranges in the issued claims of the '526, '209, and '785 patents critical, had the April 2014 Vasostrict Label been available as prior art, because the inventors admitted during prosecution that Vasostrict's pH, as disclosed as 3.4–3.6, is stable.

115. Specifically, the Kannan Declaration represented to the examiner that the pH range of 3.5–4.1, which mostly overlaps with and is inclusive of the April 2014 Vasostrict Label's pH of 3.4–3.6, has “good stability”:

Thus, the data in Figure 5 indicate that the vasopressin stability is highest in the pH range of 3.5 to 4.5, and decreases below pH 3.5. The data in Figure 6 show that the % total impurities after four weeks at 40 C° was lowest and most consistent in the range of pH 3.5 and 4.1. *Thus, the data in both Figures together indicate that vasopressin becomes less stable outside this range, at pH values above 4.1 and below 3.5.*

As I understand, the claims submitted herewith cover a vasopressin formulation at a pH of 3.5 to 4.1. *The claimed pH range of 3.5 to 4.1 reflects the good stability of vasopressin provided at pH 3.5 to 4.1 at both temperatures tested, as shown in Figures 5–6.*

Kannan Declaration at ¶¶ 17-18 (emphasis added).

116. Notably, this finding regarding the stability of pH 3.5 to 4.1 was alleged to be unexpected in view of the prior art. Specifically, based on the data provided in the Kannan Declaration, the applicant argued to the patent office that “none of the cited references disclose a pH of 3.5 to 4.1 of a vasopressin formulation” and that “[a] person of ordinary skill in the art would

not have a reasonable expectation of obtaining an acceptable level of stabilization at a pH of 3.5 to 4.1 based on the cited references.” PAR-VASO-0006453 at 8792. The applicant thus asserted that the Kannan Declaration “provides *surprising and unexpected results*” that the pH range of 3.5 to 4.1 is stable, which the applicant argued would not have been “evident from the disclosures of the cited reference because the cited references do not disclose a pH for vasopressin storage, and PPC provides no guidance for the selection of the pH range of 3.5 to 4.1 from the disclosed range of pH 2.5-4.5.” *Id.* at 792-794.

117. Thus, during the prosecution of the '239 patent, the inventors repeatedly argued to the patent office that the April 2014 Vasostrict Label's pH of 3.4–3.6, or at least part of that range, *i.e.* 3.5–3.6, “reflects the good stability of vasopressin” based on the data provided in the Kannan Declaration. The same data set forth in the Kannan Declaration that led to the inventors' conclusion that “the claimed pH range of 3.5 to 4.1 reflects the good stability” was also relied on by the inventors to later assert that a pH of 3.8 and the pH range of 3.7 to 3.9 are critical. Kannan Declaration at ¶18; PAR-VASO-0002629 at 4868–869 ('526 patent); PAR-VASO-0005400 at 5816–517 ('209 patent); PAR-VASO-0009319 at 9721–722 ('785 patent).

118. Accordingly, based on the inventors' own representation to the patent office, the April 2014 Vasostrict Label's pH of 3.4–3.6 (or at least half of it) already “reflects the good stability of vasopressin.” Thus, had the examiner relied on the April 2014 Vasostrict Label as prior art, based on the inventors' representations, the examiner could not have found a pH of 3.8 and the pH range of 3.7 to 3.9 critical to stability. This conclusion is particularly warranted because the inventors relied on the same set of experiments to reach their conclusion that the pH range of “3.5 to 4.1 reflects the good stability,” and later that the pH of 3.8 and the range of 3.7 to 3.9 also provide good stability.

b) The specifications of the '526, '209, and '785 patents confirm that the April 2014 Vasostrict Label's pH of 3.4–3.6 is stable

119. Consistent with the inventors' own representation to the patent office that the April 2014 Vasostrict Label's pH would have "good stability," the specifications of the patents-in-suit reaffirm that the pH range of 3.4 to 3.6 would be stable. For example, the specifications of the '526, '209, and '785 patents teach that a vasopressin formulation with a pH of 3.4 to 3.6 would be suitable for "Clinical Use":

Example 6

Illustrative Vasopressin Formulation for Clinical Use

A formulation for vasopressin that can be used in the clinic is detailed in TABLE 5 below:

TABLE 5		
Ingredient	Function	Amount (per mL)
Vasopressin, USP	Active Ingredient	20 Units (~0.04 mg)
Chlorobutanol, Hydrous NF	Preservative	5.0 mg
Acetic Acid, NF	pH Adjustment	To pH 3.4-3.6 (~0.22 mg)
Water for injection, USP/EP	Diluent	QS

Example 7

Illustrative Regimen for Therapeutic Use of a Vasopressin Formulation

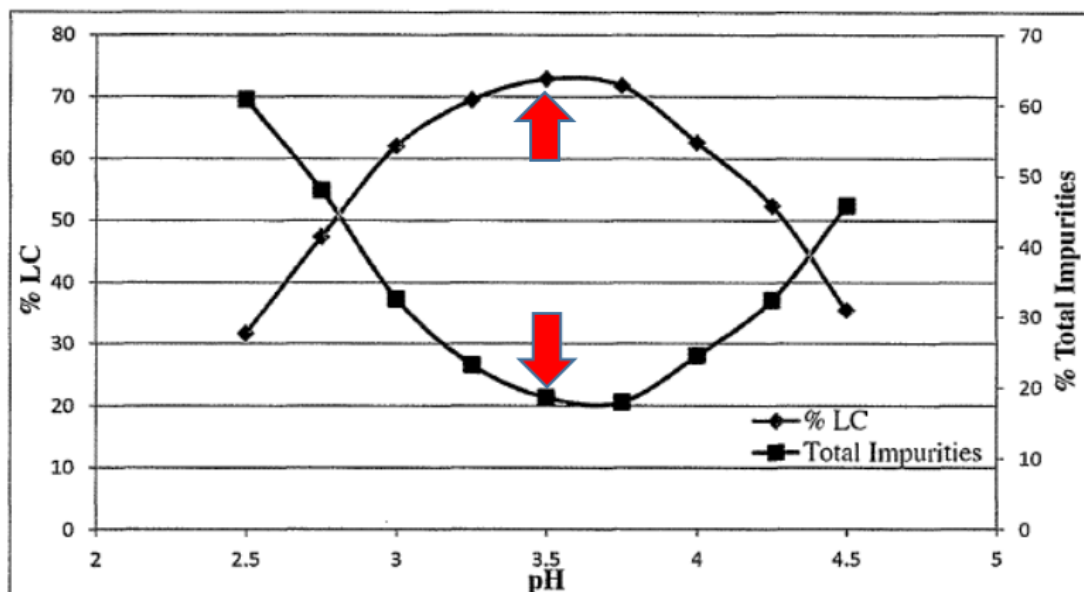
The 1 mL solution contains vasopressin 20 units/mL, chlorobutanol, NF 0.5% as a preservative, and water for injection, USP adjusted with acetic acid to pH 60 3.4-3.6.

'526 patent at 59:30-61:61; '209 patent at 59:60-62:21; '785 patent at 59:21-61:53.

120. This express teaching that pH values outside of those claimed, including the pH of the April 2014 Vasostrict Label, are suitable for practicing "the invention" of the patents-in-suit negates the inventors' claims of criticality. The '526, '209, and '785 patents also teach that "[a]t 25° C., pH 3.7 provided the highest stability for vasopressin," while "[a]t 40° C., pH 3.6 provided the highest stability for vasopressin." '526 patent at 97:22-28; '209 patent at 97:63-98:2; '785

patent at 96:65-97:6. The '526, '209, and '785 patents therefore teach that a pH of 3.6 (as taught in the April 2014 Vasostrict Label) or 3.7 provides maximum stability for vasopressin compositions. *See id.*

121. Moreover, the patents-in-suit describe additional stability data that are not reflected in the Kannan and Vandse Declarations that show that stability of vasopressin is optimal around pH 3.5 (as taught in the April 2014 Vasostrict Label). Specifically, Figure 9 of the patents-in-suit illustrate that the assay value for vasopressin was highest at pH 3.5 and the level of impurities at pH 3.5 was slightly higher but comparable to that at pH 3.75:



'526 patent Fig. 9; '209 patent Fig. 9; '785 patent Fig. 9 (annotated). Based on the data presented above, I understand that one of the named inventors, Matthew Kenney, concluded that:

The most stable pH is about 3.5. This is the pH of the current formulation therefore no peptide stability can be gained by optimizing pH.

PAR-VASO_0200880 at 887; *see also, e.g., id.* at 908. This data would have further convinced the examiner that the claimed pHs of 3.7-3.9 and 3.8 cannot be critical over the April 2014 Vasostrict's pH of 3.4-3.6.

Kenney Dep. Tr. 74:8–18; *see also, e.g.*, PAR-VASO_0028731 at 733. Par’s current, reformulated Vasostrict product also has a shelf life stability specification allowing 17% impurities after 24 months. PAR-VASO_0082707.

124. Accordingly, based on the information provided in the specifications of the ’526, ’209, and ’785 patents, a skilled person would have been informed of the inventors’ conclusion that vasopressin formulations with pH 3.4–3.6 would be stable, and in fact, that such formulations would be suitable for clinical use. This reaffirms that the examiner would not have allowed the asserted claims of the ’526, ’209, and ’785 patents over the April 2014 Vasostrict label.

c) The data set forth in the Criticality Declarations could not have shown that vasopressin formulations with the claimed pH and ranges are more stable over the April 2014 Vasostrict Label

125. It is further my opinion that the inventors could not have shown criticality of the claimed pH and ranges over Par’s commercial Vasostrict product described in the April 2014 Vasostrict Label, had it been considered as prior art by the examiner.

126. As discussed above, the April 2014 Vasostrict Label describes Par’s commercial vasopressin product, Vasostrict, which was FDA-approved in April 2014. This product was FDA-approved and commercially available for use at the time the inventors submitted their Criticality Declarations. The April 2014 Vasostrict Label describes the original formulation of Vasostrict as “contain[ing] vasopressin 20 units/mL, chlorobutanol, NF 0.5% as a preservative, and Water for Injection, USP adjusted with acetic acid to pH 3.4 – 3.6.” PAR-VASO-0006453 at 8354; *see also* PAR-VASO_0072719.

127. The April 2014 Vasostrict Label, and the original formulation of Vasostrict, have materially different compositions than the test compositions described in the Kannan Declaration. As such, a skilled person, as well as the examiner, would have known that the results of the

e.g., Kannan Decl. ¶ 4; *see also* Vandse Decl. ¶ 4. In contrast, the original Vasostrict, as described

[REDACTED]

Label § 11. Second, none of the tested formulations include chlorobutanol, an optional component of the formulations. The original Vasostrict formulation, on other hand, contains chlorobutanol. Notably, chlorobutanol was reported to affect both pH and stability. *See e.g.*, PAR-VASO_0029982 at 30008.

131. Given these material differences, a POSA or a reasonable examiner could not have concluded, based on the data provided in the Kannan Declaration that vasopressin formulations described therein at the claimed pH and ranges of 3.7-3.9 and 3.8 would be more stable over the original Vasostrict. Matthew Kenney [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Kenney Dep. Tr. 221:10-222:12.

132. As Mr. Kenney testified, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] This reaffirms my opinion that had the examiner relied on the April 2014 Vasostrict Label as prior art, she would not have permitted the issuance of the claims of the patents-in-suit, as the claimed pHs would not be critical.

133. Moreover, it's readily apparent that one cannot, based on a simple four-week stability study conducted with research samples, demonstrate superior stability of such test samples (at particular pH values) over an FDA-approved, commercial product that has been fully investigated, and critically reviewed by the FDA. Such studies provided to the FDA to demonstrate product quality include a 24-month shelf life study at refrigerated temperature and a 12-month shelf-life study at room temperature. One cannot reasonably infer the stability of a formulation over a 24-month period based on a mere four-week study conducted on research samples. The inventors agree. Dr. Sanghvi testified [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

|||

[REDACTED]

Sanghvi 30(b)(6) Dep. Tr. 231:21–232:11.

134. Dr. Vandse [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Vandse Dep. Tr. 130:18–131:11.

135. Mr. Kenney and Dr. Kannan [REDACTED] *See, e.g.,* Kenney Dep. Tr. 155:6–156:4; Kannan Dep. Tr. 204:6–17.

136. For the reasons stated above, it is my opinion that had the examiner considered the April 2014 Vasostrict Label and/or Vasostrict as prior art, she would not have allowed the asserted claims of the '526, '785, and '209 patents based on the inventors' allegations of criticality of the claimed pH and ranges.

d) There is no discernible difference in the stability data of vasopressin samples made at the claimed pH values over those made in the pH range of the April 2014 Vasostrict label

137. The inventors' criticality declarations describe the inventors' experiments directed toward demonstrating the optimal pH for stability of vasopressin formulations. *See generally* Criticality Declarations. The inventors investigated the stability of vasopressin formulations from pH 2.5 to 4.5, at 0.1 pH unit increments, upon storage under two temperature conditions: 25 °C and 40 °C, for four weeks. *See, e.g.,* Kannan Decl. ¶¶ 5, 11; *see also* Vandse Decl. ¶ 5. [REDACTED]

[REDACTED]

[REDACTED] PAR-VASO_0093626. Two types of measurements were made to test stability. First, stability was assessed by measuring the concentrations of the vasopressin in the samples after a four-week incubation period at both 25 °C and 40 °C. *See, e.g.,* Kannan Decl. ¶¶ 5–6, 11–12; *see also* Vandse Decl. ¶¶ 5–6. Second, stability

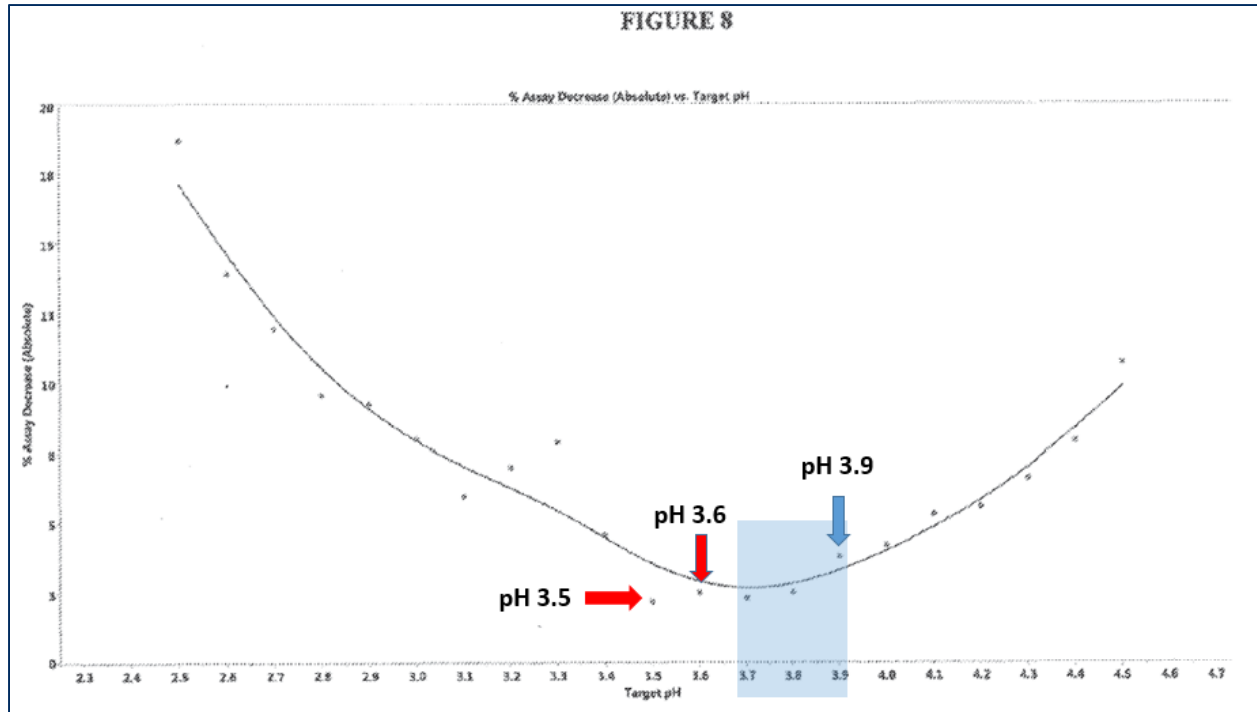
[REDACTED]

141. In fact, the percentage of decomposition at pH 3.6, based on measurements of vasopressin assay values, is *lower* than that at pH 3.9. [REDACTED]

[REDACTED] PAR-VASO_0034750. Yet, the inventors [REDACTED]

[REDACTED] In contrast, for pH 3.7 and 3.8 where the result was the same as for 3.5, *i.e.*, no decrease in assay, the curve provided by the inventors touches the x-axis, indicating the zero assay decrease, and inaccurate suggesting the best result was achieved in that range. Thus, based on this data, the inventors could not have reasonably convinced the examiner that the pH of 3.8 or the range of 3.7–3.9 is critical over (or is even meaningfully distinguishable from) that disclosed in the April 2014 Vasostrict Label, *i.e.*, pH 3.4–3.6. Excluding data points from the pH profile plot without an explanation is problematic, particularly when the excluded data point at pH 3.5 undercuts the inventors' conclusions.

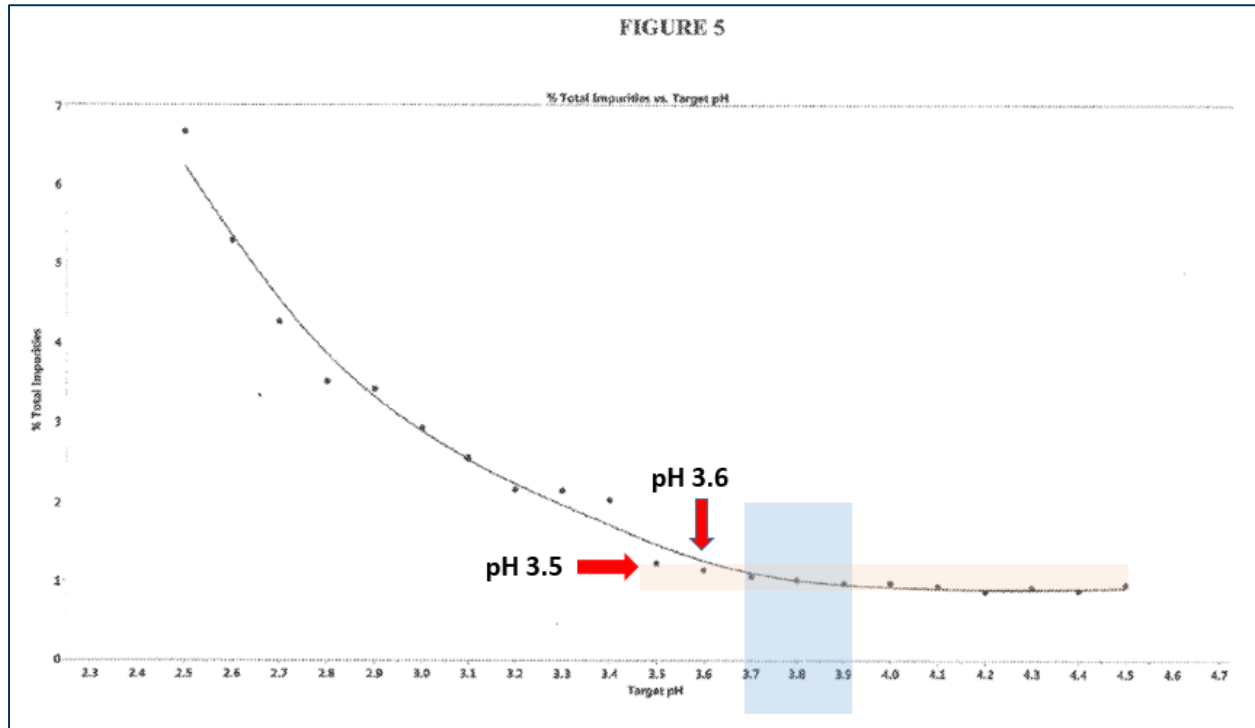
142. Consistently, the Kannan Declaration's so-called normalized data for the percentage of vasopressin remaining after incubation at 40°C for four weeks also demonstrate that the inventors could not have established any "critical effect" of pH 3.7–3.9, or pH 3.8, over pH 3.4–3.6 disclosed in the April 2014 Vasostrict Label. The following is an annotated version of Figure 8 recited in the Kannan Declaration:



Kannan Decl., Fig. 8 (annotated); *see also* Vandse Decl., Fig. 4. Figure 8 of the Kannan Declaration, even assuming that the data provided therein are reliable, does not show that the claimed pH range of pH 3.7–3.9 or pH of 3.8 is more stable than the April 2014 Vasostrict Label’s pH of 3.4–3.6. In fact, the percentages of decomposition of vasopressin at pH 3.6 and pH 3.5 are reported to be **lower** than that at pH 3.8 and 3.9, and further, the percentage of decomposition at pH 3.5 is lower than that at pH 3.7. Thus, based on this data, the examiner could not, and would not, have reached the conclusion that the claimed pH range of pH 3.7–3.9 or pH of 3.8 is critical, had the April 2014 Vasostrict Label been considered as prior art.

143. That the data set forth in the Kannan Declaration cannot meaningfully distinguish the claimed pH and ranges from that of the April 2014 Vasostrict Label’s pH 3.4–3.6 reported is also demonstrated by the impurity profile data reported therein. As with the assay results, the percentage of total impurities reported at the end of the four-week stability study demonstrates that

there is no real difference in the level of impurities between the claimed pH range of 3.7–3.9, or pH 3.8, from pH 3.4–3.6, as illustrated by Figure 5 of the Kannan Declaration:

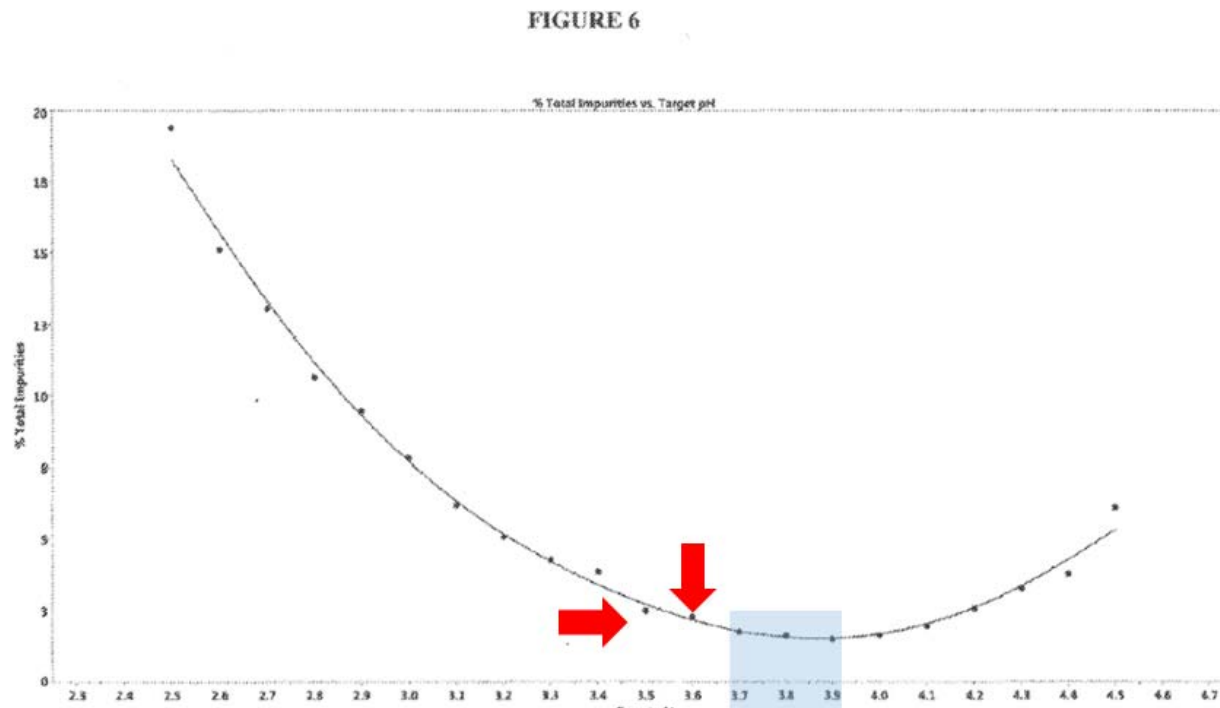


Kannan Decl., Fig. 5 (annotated); *see also* Vandse Decl., Fig. 1. As illustrated above, while there appears to be an increasing level of impurities towards the acidic end of the range disclosed in PPC, the April 2014 Vasostrict Label's pH of 3.4–3.6 (particularly pH 3.5–3.6⁵) is already pH-optimized. Thus, even if the examiner accepted this data as reliable, she would not have reached the conclusion that the claimed pH and ranges are critical based on this data, had the April 2014 Vasostrict Label been relied on as prior art.

⁵ As with the assay results reported in the Kannan Declaration, the impurities results reported for pH 2.5–3.4 cannot be reliably compared to the results reported for pH 3.5–4.5, as the inventors utilized vasopressin with a higher starting level of impurities for the set of experiments conducted at pH 2.5–3.4. This likely explains the apparent jump in the level of total impurities observed between pH 3.4 and 3.5 as these two pH values fall at the break between the two different pH studies.

144. Further, based on the review of the underlying data for this Figure 5, the sample prepared at pH 3.6 was reported to have an impurity level of 1.15% while the formulation at pH 3.8 was reported to have an impurity level of 1.02%. PAR-VASO-0002629 at 4901; PAR-VASO_0034750; PAR-VASO_0231067. Thus, the difference in the reported impurity values in the data recited in the Kannan Declaration between pH 3.8 and pH 3.6 is no more than 0.13% after storage at 25°C. *Id.* Even if this reported difference is assumed to be a genuine numerical difference (which one cannot conclude given the flaws in the data discussed below), a difference of 0.13% is one of degree, not kind.

145. The trend continues with the impurity data reported at 40 °C, which would have again confirmed to the examiner that pH 3.7–3.9 or 3.8 is not critical or meaningfully distinguishable over the April 2014 Vasostrict Label’s pH 3.4–3.6. The following is an annotated version of Figure 6 of the Kannan Declaration:



Kannan Decl., Fig. 6 (annotated); *see also* Vandse Decl., Fig. 2.

[REDACTED]

146. Figures 5 through 8 of the Kannan Declaration, discussed above, were relied on by the inventors to convince the examiner that various different claimed pH and ranges (*i.e.*, 3.5–4.1, 3.7–3.9, and 3.8) are unexpectedly⁶ stable over PPC’s pH range of 2.5–4.5. This data could not have convinced a reasonable examiner that pH of 3.7–3.9 or 3.8 would provide notable benefit in stability over the April 2014 Vasostrict Label’s pH of 3.4 to 3.6.

147. That there is no genuine difference between the assay and impurity data for the claimed pH and ranges from the April 2014 Vasostrict Label’s pH of 3.4 to 3.6 is even more clear once these values are put in context. For example, as I stated above, Par’s own shelf-life specification for its reformulated Vasostrict product claimed to embody the ’526, ’209 and ’785 patents, permits up to 17% total impurities. Kenney Dep. Tr. 74:8–12; *see also, e.g.*, PAR-VASO_0028731 at 733. Thus, the difference in impurity levels cited in support of the prosecution criticality arguments is one to two orders of magnitude below what Par considers sufficient for its commercial Vasostrict products.

148. Further, Matthew Kenney testified [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

⁶ Again, as I state in this report, there is nothing surprising about the fact vasopressin is less stable at the ends of PPC’s 2.5–4.5 range than the middle of the range. That is, in fact, precisely what a skilled person would have expected, and in fact, numerous vasopressin products, including Pitressin, Vasostrict, and American Regent’s product, were adjusted to have a pH near the middle of this range.

Kenney Dep. Tr. 63:8–19; *see also, e.g.*, PAR-VASO_0028731 at 732.

149. Accordingly, it is my opinion that the examiner would not have found the claimed pH of 3.7–3.9 or 3.8 critical, had the April 2014 Vasostrict Label been available as prior art. For this conclusion, I have assumed that the data recited in the Criticality Declarations are reliable. As I discuss in the subsequent sections of this report, the studies reported in the declarations contain significant flaws which severely hinder the ability to reach any firm conclusion that any particular pH within PPC’s range of 2.5 to 4.5 is more stable.

B. The Data Submitted by the Inventors Would Have Been Insufficient to Show Criticality Over Pitressin

150. As I stated above, I understand that Pitressin

See, e.g., PAR-VASO_0058258 at 577; PAR-VASO_0078041 at 069, 076; PAR-VASO_0120243 at 071, 078; EAGLEVAS0014051 at 352; PAR-VASO_0094514 at 515; PAR-VASO_0095005.

151. Pitressin and Vasostrict are near identical formulations.

Property (per vial)	Pitressin	Vasostrict
Vasopressin (mg/mL)		0.038
Chlorobutanol (mg)		5.0
Acetic Acid		QS to pH 3.4 to 3.6
Water for Injection (mL)	QS to 1.0	QS to 1.0
pH		3.4 to 3.6

See, e.g., PAR-VASO_0058258 at 266, 271; PAR-VASO_0072472 at 474-475; PAR-VASO-0006453 at 8354.

152. Given the near identical compositions of these two, I would expect Pitressin and Vasostrict to exhibit similar stability characteristics. I understand that Par relied on the stability data of Pitressin in its NDA filing for Vasostrict because the two products have similar stability profiles. See, e.g., PAR-VASO_0047270 at 270-272.

153. I have reviewed the inventors' deposition transcripts, and understand that [REDACTED] [REDACTED] See, e.g., Kannan Dep. Tr. 47:3–48:5; Kenney Dep. Tr. at 14:12–16:7; Sanghvi 30(b)(6) Dep. Tr. 56:15–57:9. But as discussed above, the full characterization of Pitressin, including the [REDACTED] for the drug was not provided to the patent office. Instead, only its label, which does not disclose Pitressin's pH range, nor its stability data, was provided to the examiner.

154. Pitressin is a very old product that has been used safely and effectively for nearly a century. See, e.g., EAGLEVAS0014051 at 308. Par has not yet provided any evidence that Pitressin had any safety or efficacy issues. Pitressin was known to be stable, as evidenced by its two-year room temperature shelf-life. See PAR-VASO_0058258 at 279; PAR-VASO_0219794 at 795 (Pitressin Label).

155. In view of Pitressin's long history use, its pH, and comparable stability to Vasostrict, it is my opinion that had the inventors disclosed Pitressin's full composition, the examiner would not have found the claimed pH and ranges of the patents-in-suit (3.5-4.1, 3.7-3.9, and 3.8) critical over the prior art Pitressin for the same reasons discussed above with respect to the April 2014 Vasostrict Label.

VIII. THE INVENTORS WITHHELD MATERIAL INFORMATION RELEVANT TO THE ASSERTED CLAIMS

156. In the preceding section, I provided my opinion that the examiner would not have been persuaded that the claimed pH and ranges of the patents-in-suit would be critical over the April 2014 Vasostrict Label, the original Vasostrict formulation, and Pitressin, even assuming that the underlying data set forth in the Kannan Declaration is reliable.

157. As set forth in this section, the inventors withheld certain key information necessary to understand the reliability of the data set forth in the Kannan Declaration. My review of that non-disclosed information leads me to conclude that the experiments described in the Kannan Declaration have critical design flaws, and were likely manipulated to provide skewed and more favorable presentations towards the claimed pH and ranges over the prior art.

158. Further, in addition to the April 2014 Vasostrict Label and Pitressin discussed in the preceding section, I set forth below other key information that the inventors appear to have been aware of, but did not disclose to the patent office, which would have been material to assessing whether the claimed formulations of the patents-in-suit indeed have critical advantages over (or are even distinguishable from) the prior art.

A. [REDACTED]

159. [REDACTED]

[REDACTED] Specifically, for the data provided in the Kannan Declaration, the inventors performed two sets of experiments. The first set of experiments, which were initiated in March 2015, investigated the stability of vasopressin solutions within a pH range from 3.5–4.5. Roughly eight months later in November 2015, a second set of experiments was initiated to investigate the stability of vasopressin solutions within a pH from 2.5–3.4. *See* PAR-VASO_0059950 at 59988,

[REDACTED]

[REDACTED]

PAR-VASO_0034748.

170. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] *See generally* Kannan Decl.

171. While the inventors withheld [REDACTED] from the examiner, they did produce what they referred to as “normalized” *assay* data. As illustrated below, the starting

[REDACTED]

175. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] This selective production was made despite the fact there is no reasonable scientific basis to approach normalization of assay and impurity data differently. At a minimum, the impurity data should have been normalized to account for the differences in composition of the two different sets of solutions prepared for the pH study. The only reasonable conclusion based on the selective production, therefore, is that the inventors only produced normalized data that supported their criticality arguments.

176. *None* of the samples prepared for the claimed pH values of the patents-in-suit were part of the second set of experiments (pH 2.5-3.4) that contained substantially higher levels of impurities at the beginning of stability study. It is my opinion that this is unlikely to be coincidental. At a minimum, due to the significant lack of proper controls in the experiments reflected in the Criticality Declarations, one cannot reliably conclude, based on the data disclosed, that any particular pH in-between the studied range of 2.5-4.5 is more or less stable over another pH.

177. For the same reasons, it is my opinion that had the normalized impurity data been disclosed to the examiner, the examiner would not have accepted the inventors' assertion of criticality of the claimed pH and ranges over the prior art and would not have allowed the claims of the patents-in-suit.

[REDACTED]

B. The Inventors Withheld Information That Would Have Revealed Important Flaws Regarding the Experiments Set Forth In the Kannan Declaration

178. [REDACTED]

[REDACTED]

[REDACTED]

179. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

180. An acetate buffer was also used for the underlying experiments performed for the Kannan Declaration. *See, e.g.*, Kannan Decl. ¶¶ 4, 10.

181. [REDACTED]

[REDACTED] PAR-

VASO_0200880 at 903-904. [REDACTED]

[REDACTED]

[REDACTED] *Id.* at 904.

182. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

185. [REDACTED]

[REDACTED]

[REDACTED]

186. It is my opinion that had a reasonable examiner been informed of [REDACTED] [REDACTED] she could not have accepted the inventors' representation to the Patent Office that the claimed pH ranges and pH of the '526, '785, and '209 patents (3.7-3.9, 3.8) are critical. Instead, the examiner may have believed that pH 3.5 is not less stable relative to the claimed pH values, [REDACTED]

187. In addition, I am aware that, contrary to the arguments made in support of the criticality of pH 3.8 and 3.7 to 3.9 over the prior art, [REDACTED]

[REDACTED]

[REDACTED]

PAR_VASO_0072472 at 478-479.

188. This representation was not disclosed to the examiner. The information is clearly material, as if the examiner had been made aware that [REDACTED] [REDACTED] [REDACTED] she would not have found the claimed pH ranges and pH of the '526, '785, and '209 patents (3.7-3.9, 3.8) critical.

189. Further, the inventors appear to have been aware of, but did not disclose, [REDACTED]

[REDACTED]

[REDACTED]

193. Another named inventor, Dr. Sanghvi, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Sanghvi Dep. Tr. 101:23–102:14.

194. Mr. Kenney's [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

195. As I discuss in the subsequent sections of this report, the presence of variability would have precluded a reasonable examiner (and skilled persons) from drawing any conclusions of criticality of any particular pH values over PPC's range of 2.5-4.5, the April 2014 Vasostrict,

Pitressin, or Vasopressin. Yet, the Criticality Declarations do not disclose or account for the variability sourced from the USP standard or other measurement variability.

IX. THE CLAIMED PH RANGES ARE NOT CRITICAL OVER THE PRIOR ART IN ANY EVENT

A. The Data Set Forth in the Criticality Declarations Are Unreliable Due to Critical Design Flaws

196. As discussed above, the Kannan Declaration describes the inventors' experiments intended to demonstrate the optimal pH for stability of vasopressin formulations. *See generally* Criticality Declarations. The inventors tested vasopressin formulations from pH 2.5 to 4.5 at 0.1 pH unit increments in two different sets of experiments, and stored them under two temperature conditions, at 25°C or at 40°C, for four weeks. *See, e.g.,* Kannan Decl. ¶¶ 5, 11; *see also* Vandse Decl. Two types of measurements were made to test stability. First, stability was assessed directly by measuring the concentrations of the vasopressin in the samples after a four-week incubation period at both 25 °C and 40 °C. *See, e.g.,* Kannan Decl. ¶¶ 5–6, 11–12; *see also* Vandse Decl. Second, stability was also assessed by measuring the levels of impurities at the four week time point. *See, e.g.,* Kannan Decl. ¶¶ 5–6, 11–12; *see also* Vandse Decl.

197. It is my opinion that the inventors' experiments described in the Kannan Declaration cannot meaningfully inform a skilled person of any genuine difference in stability of the claimed pH ranges or value (*i.e.*, 3.5–4.1, 3.7–3.9, and 3.8), from the broader pH range of 2.5–4.5 (or from Vasopressin and Pitressin's target pH of 3.4–3.6), due to a number of significant design flaws in the experimentation.

198. As I stated above, in all experimental situations, designing and carrying out experiments with the proper controls to minimize variability is critical in order to achieve reliable and informative results. When the variability in an experiment is erroneously assumed to be controlled, accounted for, or even ignored, the experimental results obtained are unreliable or



Date: November 15, 2019

A handwritten signature in cursive script that reads "Leonard J. Chyall".

Leonard J. Chyall, Ph.D

EXHIBIT B

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

PAR PHARMACEUTICAL, INC., PAR
STERILE PRODUCTS, LLC, and ENDO
PAR INNOVATION COMPANY, LLC,

Plaintiffs,

v.

EAGLE PHARMACEUTICALS INC.,

Defendant.

C.A. No. 18-00823-CFC

REPLY EXPERT REPORT OF LEONARD J. CHYALL, PH.D.

VI. LEGAL STANDARDS

11. I set forth the legal standards applicable to my analysis in my Opening Report. I incorporate those standards herein by reference. I have continued to apply those legal standards in this Reply Report.

VII. THE CLAIMS OF THE PATENTS-AT-ISSUE ARE NOT CRITICAL OVER THE PRIOR ART

12. For the reasons set forth in my Opening Report (Section VII), it is my opinion that the data set forth in the Criticality Declarations still would not have been and is not sufficient to establish criticality of the claimed pH and ranges (*i.e.*, 3.5–4.1, 3.7–3.9, and 3.8), had the April 2014 Vasostrict Label, Pitressin, and/or Vasostrict been available to the Examiner of the patents-at-issue. Furthermore, it is my opinion that this data does not show criticality of any pH claim limitation over the prior art discussed by Dr. Kirsch, including the withheld references as well as PPC and the American Regent's Label, among others.

13. I have reviewed Dr. Kirsch's contrary opinions in his Rebuttal Report, and disagree with them for at least the following reasons.

A. The Inventors and Par Declared that a Number of Different pH Ranges Are Critical

14. Dr. Kirsch asserts that [REDACTED]

[REDACTED] Kirsch Rebuttal Report ¶ 312. I disagree.

15. The context in which the Kannan Declaration was submitted to the Examiner during prosecution of the '239 patent is informative. Before the Kannan Declaration was submitted, the Examiner rejected all the pending claims of the '239 patent as obvious over the prior art. 11/22/2016 Non-Final Rejection, '239 Prosecution History (PAR-VASO-0008735-755). The

18. The Examiner accepted these representations from the inventors and their attorney and allowed the claims of the '239 patent. In allowing the claims, the Examiner noted that the Kannan Declaration is "sufficient to overcome an obviousness rejection over Pharmaceutical Partners of Canada because it establishes *the criticality of the claimed pH range of 3.5 to 4.1.*" 7/11/2017 Notice of Allowability, '239 Prosecution History (PAR-VASO-0009273-9276) (emphasis added). This is the only reason for issuing the claims that the Examiner provided. *See id.*

19. Despite this clear record, Dr. Kirsch nevertheless appears to disagree on the basis that the inventors and applicant did not explicitly use the word "critical". I disagree with that narrow reading of the prosecution history. The inventors and applicant conveyed their assertion of criticality by asserting, as noted above, that POSA "would not be motivated to develop" a formulation with the pH range of 3.5 to 4.1, that that pH range provided "*surprising and unexpected*" results, and that the prior art "teach[es] away from using" that pH range. 5/22/2017 Argument/Remarks, '239 Prosecution History (PAR-VASO-0008791-8798). I understand that criticality and unexpected results are related legal concepts, and that one way of establishing criticality of a claimed range is by showing that the claimed range achieves unexpected results. The Examiner understood the inventors' and applicant's assertion to be one of criticality, accepting that those assertions "*established the criticality of the claimed pH range of 3.5 to 4.1.*" 7/11/2017 Notice of Allowability, '239 Prosecution History (PAR-VASO-0009273-9276) (emphasis added). POSA reviewing the file history would likewise understand the statements as an assertion of the criticality of the pH range. I note that neither the inventors nor the applicant ever noted any disagreement or objection, or offered any correction or clarification, regarding the examiner's stated understanding.

20. Dr. Kirsch has not explained what other than criticality of the pH range the inventors and applicants were asserting, or how the inventors' and the applicant's assertions would not convey "criticality." Regardless, Par inconsistently argued that several different pH values are important for stability of vasopressin (*i.e.*, 3.5-4.1, 3.7-3.9, and 3.8) in order to distinguish the claims from the prior art and secure their patent claims. Whether or not the phrase "critical" was explicitly stated has no impact on my analysis.

21. Finally, it cannot be disputed that the Examiner understood the inventors to assert that the claimed pH range of 3.5 to 4.1 is critical. Yet, neither the inventors nor the applicant sought to correct this understanding, to the extent the Examiner misunderstood their representations regarding the claimed pH.

B. Dr. Kirsch's Assertions Regarding Prosecution of the '209 and '785 Patents Are Flawed

22. In paragraphs ¶¶ 314–316 of the Kirsch Rebuttal Report, Dr. Kirsch appears to suggest that [REDACTED]

[REDACTED] I disagree.

23. Example 15 provides the 15-month room temperature stability data for a drug formulation of Table 51, which has the following composition:

TABLE 51		
Drug Product Composition		
Ingredient	Function	Quantity (mg/mL)
Vasopressin, USP	Active	20 Units
Sodium Acetate Trihydrate, USP	Buffer	1.36
Sodium Hydroxide NF/EP	pH Adjuster	QS for pH adjustment to pH 3.8
Hydrochloric Acid, NF/EP	pH Adjuster	QS for pH adjustment to pH 3.8
Water for Injection	Solvent	QS to 1 mL

[REDACTED]

explanation for withholding the study and Dr. Kirsch does not provide any explanation. Under these circumstances, the only reasonable conclusion based on the selective production is that the inventors withheld it because their internal and undisclosed conclusion that pH 3.5 is the most stable pH for vasopressin formulations with an acetate buffer would have undermined their criticality positions as set forth during prosecution in the Criticality Declarations.

B. The Inventors Withheld Other Material Information

60. In paragraph 343 of his Rebuttal Report, Dr. Kirsch opines that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Kirsch Rebuttal Report ¶ 343. I disagree because had the Examiner been provided with this information, the Examiner would have been unlikely to accept the inventors' criticality allegations. This conclusion is further strengthened when the nondisclosed information and data are viewed in whole. Specifically, if the Examiner was provided with all of the withheld information, including the [REDACTED]

[REDACTED]

[REDACTED] among others—the Examiner could not have reasonably concluded that the claimed pH values were critical. Such comprehensive disclosure would have revealed to the Examiner that Par has asserted that five different pH ranges (3.4–3.6, 3.5–4.1, 3.7–3.8, 3.7–3.9, and 3.8) are critical for stability of vasopressin, and that holding these inconsistent positions was only possible because there is no single *critical* pH, as Par now asserts. In other words, if indeed there were a *critical* pH that exhibited a stability difference in kind, not in mere degree, from the other pH values, it would not have been possible to demonstrate that five distinct pH ranges (3.4–3.6, 3.5–4.1, 3.7–3.8, 3.7–3.9, and 3.8) can be presented as if they are critical.

[REDACTED]

the Criticality Declarations, where the second set of the experiments (at pH 2.5-3.4) that used the older lot of vasopressin started off with a higher measured assay value than the first set of experiments at pH 3.5-4.5. Because the amount of vasopressin is not expected to increase for an older lot of vasopressin, the higher starting assay values for the second set does not make sense. This highlights the unreliability of the data disclosed in the Criticality Declarations.

90. Because the inventors did not account for all material variability present in their data, paragraphs 373–376 of Dr. Kirsch’s Rebuttal Report miss the point. Rather, the fact that the inventors disclosed one source of variability (the precision of replicate HPLC injections of the same HPLC sample), but ignored the other sources (such as the variability inherent in the USP standard), highlights the arbitrary approach the inventors took in disclosing information to the Examiner. Such selective production of information cannot be explained by any scientific principles, nor does Dr. Kirsch attempt to provide an alternative explanation. In this context, the only reasonable conclusion is that the inventors were driven to selectively produce and withhold information in order to support their criticality allegations.

H. Dr. Kirsch’s Statistical Analysis is Flawed Because He Does Not Consider All Sources of Variability

91. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

While instrumental precision is one variable, there are others such as variability in sample composition that would

94. Finally, I note a generally accepted method to determine whether or not two measured values are statistically different from one another is to conduct a t-test on the differences of the means of the values. (Henry L. Alder et. al., *Introduction to Probability and Statistics*, Chapter 10). However, without replicate analysis on the actual values being compared, there is no way to determine the mean values, standard deviations, or to apply the appropriate confidence limit according to the number of replicates. Because of the lack of replicate values for the pH impurity values in the Criticality Declarations or elsewhere, a proper statistical analysis is not possible. Therefore, no conclusion can be drawn that the differences in total impurities between for example, pH 3.6 and pH 3.8 are statistically significant.

95. Dr. Kirsch's Rebuttal Report leaves unanswered why the inventors withheld multiple different sources of variability, including the variability inherent in the USP standard. Likewise, his statistical analysis set forth in paragraphs 377–389 ignores these sources of variability. Having failed to consider all sources of variability, Dr. Kirsch's statistical analysis necessarily overstates the statistical power of the data set forth in the Criticality Declarations. Accordingly, I disagree with his conclusion set forth in paragraphs 377–389.

1. The Examiner was Misled Because the Inventors Selectively Produced Information Regarding Variability

96. Regarding Dr. Kirsch's opinion set forth in paragraph 379 of his Rebuttal Report, the fact that the Examiner requested statistical analysis and error bars for the data in the Criticality Declarations at one point does not render the inventors' selective production of sources of variability any less misleading. To the contrary, having expressly made the request for statistical analysis and error bars, it is evident that the Examiner relied on the inventors to accurately and comprehensively disclose the variability present in the data so that she could come to a reliable conclusion. The inventors' subsequent selective production, which only disclosed the intra-assay

[REDACTED]

variability of the reference standard, but without disclosing, for example, the inherent variability in the purity of the USP standard as evident from the difference in the starting assay values of the first and second sets of experiments, left the examiner unable to properly evaluate the information provided, and overstated the statistical power of the data set forth in the Criticality Declarations. For this reason, I disagree that “it is reasonable to conclude that the Kannan I Declaration, which reported Par’s validation of vasopressin assay precision, adequately addressed and satisfied the examiner’s concerns regarding statistical analysis.” See Kirsch Rebuttal Report ¶ 379.

2. Dr. Kirsch’s Impurity Analysis [REDACTED]

97. Regarding paragraphs 388–389 of his Rebuttal Report, Dr. Kirsch [REDACTED]

[REDACTED] As I noted above, this approach is not only directly inconsistent with the position that Par took before the Court during claim construction, but it is also scientifically unjustified.

98. Nor has Dr. Kirsch provided any evidence that [REDACTED]

[REDACTED]

[REDACTED] In fact, during prosecution of the ’239 patent, one of the inventors, Sunil Vandse, submitted a declaration to the Examiner asserting that the stability results obtained at 5 °C were “surprising and unexpected [] over the experiment’s performed at 25 C and 40 C”:

[REDACTED]

assertion of infringement of the claims of the patents-at-issue against Eagle's ANDA product itself establishes materiality of the April 2014 Vasostrict Label. Further, because the inventors submitted a false declaration regarding this label, I understand that the misconduct itself establishes materiality.

120. His primary basis is that the "0-2% vasopressin degradation products" limitation is not specifically disclosed in the label, and therefore the Examiner would not have found the label to be anticipatory. I disagree. Dr. Kirsch ignores the prosecution history of the '239 patent, which shows that the Examiner repeatedly found all of the limitations drawn to the level impurities to be "an inherent feature of the prior art formulation." 10/21/2015 Final Rejection, '239 Prosecution History (PAR-VASO-0008323-335); 1/11/2016 Non-Final Rejection, '239 Prosecution History (PAR-VASO-0008417-429); 5/12/2016 Final Rejection, '239 Prosecution History (PAR-VASO-0008661-8675). Likewise, the Examiner also found that the 0–2% degradation products limitation is disclosed inherently by PPC. PAR-VASO-0008426. The conclusion necessarily applies to the the April 2014 Vasostrict Label, which recites a narrower pH range than PPC. *Compare* PAR-VASO-0008426, *with* PAR-VASO-0008327. Thus, the Examiner would have, consistent with her other findings, found the "0-2% vasopressin degradation products" limitation to be an inherent feature.

121. Dr. Kirsch also faults Dr. Park's obviousness analysis for relying [REDACTED]

[REDACTED]

[REDACTED] Kirsch Rebuttal Report ¶ 158. This opinion is directly contrary to Dr. Kirsch's approach on infringement. For his infringement analysis, I understand that Dr. Kirsch has relied [REDACTED]

[REDACTED]



Date: January 20, 2020

Leonard J. Chyall

Leonard J. Chyall

EXHIBIT C

Leonard J. Chyall, Ph.D.

Education

B.A. (Chemistry), 1986, Oberlin College, Oberlin, OH

Ph.D. (Chemistry), 1991, University of Minnesota, Minneapolis, MN

Postdoctoral Fellow, 1992-1996, Purdue University, West Lafayette, IN

Pharmaceutical Solids and Regulatory Affairs Short Course, Purdue University, 2001

Employment

**May 2011 – Chyall Pharmaceutical Consulting, LLC; West Lafayette, Indiana
President and Consultant**

Independent consultant serving the pharmaceutical industry. Expertise in synthetic chemistry, and analytical testing of drug substances and drug products. Services directed toward scientific data and document review, laboratory testing, and technical assistance with IP matters.

2000-2011 Aptuit, Inc. (formerly SSCI, Inc.), West Lafayette, Indiana

Director (August 2010 – May 2011)

Principal (January 2007 – July 2010)

Senior Research Investigator (2003 - 2006)

Research Investigator (2000 - 2003)

Project manager and group leader for external client projects involving various aspects of organic and analytical chemistry. These projects involve the development of new products (primarily pharmaceuticals) or providing scientific consulting to support patent litigation, counterfeit analysis or tampering analysis projects. Leader of a department responsible for fee-for-service laboratory testing and consulting services. Responsible for business development, client relations, and strategic planning of the business. Administrative supervisor for numerous chemists throughout my tenure with the organization.

**1996-2000 Great Lakes Chemical (now Chemtura), West Lafayette, Indiana
Research Chemist**

Lead Scientist for a new technology development program in the GLCC Corporate R&D division. Technology Coordinator for contract research programs. Project Leader for a new product development project in GLCC Polymer Additives R&D.

Representative Technical Skills

Analytical Chemistry

- Mass Spectrometry
 - Triple Quadrupole Systems
 - Ion Cyclotron Resonance MS
 - Ion-Molecule Chemistry
- Chromatography (HPLC, MPLC, TLC and preparative chromatography)
- Infrared (IR) and Raman Spectrometry
- NMR spectroscopy
- Spectrophotometry
- Solubility and dissolution testing
 - USP dissolution testing
 - Intrinsic dissolution rate studies
- Powder dissolution testing
- pH measurements
- Potentiometric titrations
- Karl Fischer titration

Organic Chemistry

- Synthetic chemistry
 - mg to kg scale laboratory reactions
 - high pressure reactions
 - air-sensitive procedures
- Crystallization methods
- Enantiomer resolutions
- Polymorph, salt and cocrystal screening and characterization

Solid Form Analytical Techniques

- X-ray powder diffraction (XRPD)
- Thermogravimetric analyses (TGA)
- Differential scanning calorimetry (DSC)
- Optical microscopy
- Moisture sorption/desorption analyses

Professional Affiliations and Activities

- American Chemical Society
- American Association of Pharmaceutical Scientists
- Purdue Research Park Life Sciences Executive Council
- Guest Lecturer, Chemistry Department, Purdue University (Undergraduate Organic Chemistry Courses) 2016 – 2017.

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Invited Lectures

1. "Environmentally Friendly Fire Suppression Technology." Department of Chemistry, Purdue University, West Lafayette, IN. April 8, 1997.
2. "The Proton Affinity and Absolute Heat of Formation of Trifluoromethanol." Joint Institute Laboratory for Astrophysics, University of Colorado, Boulder, CO. March 1, 1996.
3. "Understanding the Atmospheric Fate of Hydrofluorocarbons: Thermochemistry of Trifluoromethanol." Aeronomy Laboratory, National Oceanic and Atmospheric Administration, Boulder, CO. February 29, 1996.

Dissertation

Chyall, L. J. The synthesis and thermal rearrangements of 7,7-dibromo-*trans*-bicyclo[4.1.0]hept-3-ene and 7,7-dichloro-*trans*-bicyclo[4.1.0]hept-3-ene. (1991) 192 pp. Avail.: Univ. Microfilms Int., Order No. DA9209417 From: Diss. Abstr. Int. B 1992, 52(10), 5264.

EXHIBIT D

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

PAR PHARMACEUTICAL, INC., PAR
STERILE PRODUCTS, LLC, and ENDO
PAR INNOVATION COMPANY, LLC,
Plaintiffs,

v.

EAGLE PHARMACEUTICALS INC.,
Defendant.

C.A. No. 18-00823-CFC

OPENING EXPERT REPORT OF CARMEN A. CROSS, M.D.

45. Especially given this well-developed art regarding the use of vasopressin, the labeling for original Vasostrict®—drafted based on earlier art literature—instructs the practice of the claimed clinical steps.

46. Furthermore, Pitressin® and Vasostrict® were used by practitioners in the field to practice the clinical elements, i.e., the claimed methods, of the asserted and/or challenged claims. In particular, Par has admitted that Pitressin® was used to practice the methods recited by the clinical elements and represented to the FDA that Pitressin®, among other products, has been used in that way. Furthermore, the original prior art Vasostrict® formulation was used pursuant to its labeling to practice the clinical elements. In addition, other comparable vasopressin products available to clinicians prior to the asserted and/or challenged claims were used to treat hypotension in the same manner

47. In this regard, it is also my view that the prior art Pitressin® and Vasostrict® formulations, and the originally approved product label and instructions for use for Vasostrict® published in April 2014 (the “April 2014 Vasostrict® Label”), would have been material to the prosecution of the patents-in-suit, given their use for, or disclosure of, the clinical elements of the claims of those patents.

48. I am not providing an ultimate opinion on the validity of the asserted and/or challenged claims of the patents-in-suit or any opinion regarding the ’785 patent, which does not contain clinical elements.

X. BACKGROUND

49. The clinical elements of the asserted and/or challenged claims merely claim the longstanding use of vasopressin to treat hypotension, including vasodilatory shock. Not only was this use described by the literature, but it was specifically recommended to doctors for use in treating such conditions. Consistent with this history, vasopressin products had long been

XV. THE APRIL 2014 VASOSTRICT® LABEL, PITRESSIN®, AND VASOSTRICT® ARE MATERIAL PRIOR ART TO THE CLINICAL ELEMENTS OF THE '526, '209, AND '239 PATENTS

243. I understand that certain prior art, including the April 2014 Vasostrict® Label, as well as the properties of Pitressin® and Vasostrict®, were withheld or excluded from prosecution of the asserted and/or challenged claims.

A. April 2014 Vasostrict® Label

244. As set forth above, the Patent Office rejected all pending claims of the '239 patent over the April 2014 Vasostrict® Label. Furthermore, as set forth above, the April 2014 Vasostrict® Label discloses each and every clinical element of the claims of the '239 patent, as well as the '526 and '209 patents. In addition, as set forth above, the inventors and Par did not challenge the substance of the Examiner's findings that the April 2014 Vasostrict® Label discloses each and every limitation of the asserted claims.

245. Instead of disputing that the April 2014 Vasostrict® Label disclosed the elements of the pending claims, I understand that Par and the inventors argued that this reference was not available as prior art because the relevant information in the label was invented by the inventors of the '239 patent and provided to the FDA of inclusion therein. *See, e.g.,* PAR-VASO-0008384—86.

246. As discussed in greater detail above, the methods of treatment recited in the '239, '526, and '209 patents were well within the prior art before the '239 patent. Clinicians had long been using Pitressin® and other vasopressin products in a manner claimed by the pending and issued claims. In addition, these methods were long taught by standard medicine guides and treatment standards from well before the asserted and/or challenged patents. Consistent with this prior use and well-developed literature, the inventors confirmed that they did not invent the clinical

elements analyzed herein. *See, e.g.*, Kannan Deposition Transcript at 252:3–17, 254:6–18; Kenney Deposition Transcript at 39:14–20, 40:11–17, 41:19–42:2.

247. Because the April 2014 Vasostrict® Label expressly discloses the clinical elements of each of the asserted and/or challenged claims of the '239, '526, and '209 patents, I understand that it is material prior art to patentability of the asserted and/or challenged claims of those patents. Had the Examiner considered the April 2014 Vasostrict® Label, she should have found the clinical elements of the asserted and/or challenged claims to be in the prior art.

248. In addition, after accepting those arguments regarding the invention, the Examiner cited a number of additional references as disclosing the clinical elements of the '239 patent as well as the same references for the same disclosures in the prosecutions of the '526 and '209 patents. In particular, the patent Examiner cited:

- Treschan for the use of vasopressin to treat vasodilatory shock, septic shock, and post-cardiotomy shock, as well as the infusion doses to do so, the rapid effect of vasopressin administration, and limiting doses through routine optimization
- Russell, Buck, and Young for the dilution of vasopressin to a final concentration of between 0.1 and 1 unit/mL with 5% dextrose in water or normal saline for intravenous infusion

PAR-VASO-0008737–45; PAR-VASO-0004766–75; PAR-VASO-0005733–41. In addition to these references, the Patent Office cited a number of additional references, such as PPC, for disclosures regarding the composition elements or other handling aspects of the asserted and/or challenged claims. *See, e.g.*, PAR-VASO-0008737–45; PAR-VASO-0004766–75; PAR-VASO-0005733–41.

249. The April 2014 Vasostrict® Label, however, is closer prior art to the asserted and/or challenged claims of the '239, '526, and '209 patents because the disclosure of the April 2014 Vasostrict® Label is essentially word-for-word the same as the claimed clinical elements.

B. Pitressin®

250. As set forth above, Pitressin® was widely used to practice the clinical elements of the claims prior to the earliest effective filing dates of the asserted and/or challenged patents.

251. Therefore, information about this prior art product would have been material to the practice of the clinical elements of the asserted and/or challenged claims.

C. Vasostrict®

252. As set forth above, original Vasostrict® was indicated for the treatment of hypotension and was distributed with labeling instructing the practice of the claimed clinical elements exactly. Original Vasostrict® was also used to practice the clinical elements according to its product labeling.

253. Therefore, for the same reasons as set forth for the April 2014 Vasostrict® Label above, the original Vasostrict® product and its properties are material to the practicing of the clinical elements of the asserted and/or challenged claims.



Dated: November 14, 2019

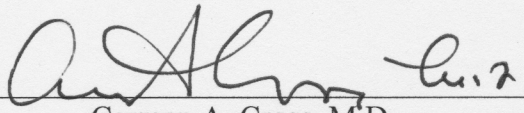

Carmen A. Cross, M.D.

EXHIBIT E

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

PAR PHARMACEUTICAL, INC., PAR
STERILE PRODUCTS, LLC, and ENDO
PAR INNOVATION COMPANY, LLC,
Plaintiffs,

v.

EAGLE PHARMACEUTICALS INC.,
Defendant.

C.A. No. 18-00823-CFC

OPENING EXPERT REPORT OF KINAM PARK, PH.D.

- September 2014 Vasostrict® Label (anticipation);
- September 2014 Vasostrict® Label, alone or in combination with Intravenous Medications 2013, Russell 2008, Treschan 2006, and/or WO '907 (obviousness);
- March 2015 Vasostrict® Label (anticipation);
- March 2015 Vasostrict® Label, alone or in combination with Intravenous Medications 2013, Russell 2008, Treschan 2006, and/or WO '907 (obviousness);
- PPC, alone or in combination with Intravenous Medications 2013, Russell 2008, Treschan 2006, WO '907, and/or WHO Standard 2013 (obviousness);
- Prior art vasopressin labels,³³ alone or in combination with Intravenous Medications 2013, Russell 2008, Treschan 2006, WO '907,³⁴ and/or WHO Standard 2013 (obviousness);
- The HPLC claim limitations are further obvious in view of Bi 1999, Wilczynska 2002, and/or Yanagisawa 1998;
- The “discard[] a vial . . . at least 48 hours after a first puncture” limitation of the '239 patent is further obvious in view of Joint Commission 2014 Misuse of Vials and SEA 2014.

XIV. THE EXCLUDED AND WITHHELD PRIOR ART REFERENCES AND INFORMATION ARE MATERIAL TO THE PATENTABILITY OF THE ASSERTED AND/OR CHALLENGED CLAIMS

377. I have also been asked to opine on the materiality of prior art that was withheld or excluded based on statements made during prosecution by the inventors as to the patentability of the claims. In particular, I have analyzed the: April 2014 Vasostrict® Label; full Pitressin® composition properties; properties of higher pH lots of Pitressin®; and information concerning the reliability of the inventors' prosecution testing.

³³ Including American Regent Label; Fresenius Label; Pitressin® Label 2012; Pitressin® Label 2010; Cardinal Label.

³⁴ In addition to the further clinical prior art discussed by Dr. Cross, including Liverpool Hospital 2014, BH Medicine Guide, Dellinger 2013, AHFS 2011, Argenziano 1997, and other similar references discussed by Dr. Cross.

A. April 2014 Vasostrict® Label

378. It is my opinion that the April 2014 Vasostrict® Label that the applicants argued was not prior art would have been material to the patentability of the challenged claims. Furthermore, this Label is closer prior art to the challenged claims than the PPC reference, among others, cited by the examiner during prosecution following the disqualification of the April 2014 Vasostrict® Label.

1. The April 2014 Vasostrict® Label Is Material Prior Art

379. I understand from Dr. Cross's analysis that the April 2014 Vasostrict® Label discloses expressly each and every clinical element of the challenged claims of the '526, '209, '239, and '785 patents. I rely on his opinion and his conclusions regarding the clinical elements of the challenged claims and the April 2014 Vasostrict® Label.

380. In particular, from Dr. Cross's analysis, I understand that the April 2014 Vasostrict® Label discloses, among other aspects, the clinical uses recited by the claims, dilution of vasopressin formulations, and titration and tapering steps as recited by the asserted and/or challenged claims of the '526, '209, and '239 patents.

381. As set forth above, it is my opinion—consistent with the unrebutted findings of the patent examiner—that this Label disclosed each and every composition elements of the challenged claims and, to the extent it did not, rendered any remaining limitation obvious.

382. Foremost, as discussed above, the April 2014 Vasostrict® Label described a unit dosage form with 0.038 mg/mL vasopressin (20 units/mL), chlorobutanol, acetic acid for pH adjustment, and water for injection. *See, e.g.*, April 2014 Vasostrict® Label § 11. Therefore, this Label expressly taught the chemical components of the unit dosage forms recited by the challenged claims of the '526, '209, '239, and '785 patent.

383. The April 2014 Vasostrict® Label also disclosed, as previously discussed, a pH range of 3.4 to 3.6. This pH range is narrower than, and overlapping with, the recited range in the challenged claims of the '239 patent. In addition, this pH range abuts that recited in the '209 and '785 patents—3.7 to 3.9—and is just 0.2 pH units away from that recited in the '526 patent.

384. This pH range of the April 2014 Vasostrict® Label is closer to the claimed pH ranges and values than the broader range of pH 2.5 to 4.5 disclosed by PPC (cited by the examiner), among other references in the prior art. First, the range of 3.4 to 3.6 is one-seventh as broad as the range of PPC that was before the patent examiner. Second, this narrow range, as stated, is very close to what is recited by the challenged claims—much closer than much of PPC's pH range—and within the very pH region that Par now alleges is the most stable for vasopressin for optimization. *See, e.g.*, PAR-VASO-0000106 ('526 Patent Examples 9 & 10). In combination, this narrower, closer range would have served to focus a POSA's pH optimization efforts on a narrower set of pH values, namely just that of the April 2014 Vasostrict® Label and the abutting values within a limited number of pH units. When limited as such, this routine process would have become even less complicated and a POSA would easily have found any purported optimum value, including those alleged to be critical by Par and recited by the claims.

385. In addition, as discussed in detail above, the April 2014 Vasostrict® Label—as confirmed by the examiner—by virtue of expressly disclosing the same chemical components as the asserted and/or challenged claims, also inherently disclosed the impurities, stability, and degradation products limitations of the asserted and/or challenged claims. Furthermore, the data for the original Vasostrict® product disclosed in the April 2014 Vasostrict® Label, *see* § 11, described above demonstrated that this formulation actually does satisfy the various impurities, stability, and degradation products limitations, particularly in light of Par's infringement

allegations against Eagle. These specific stability and impurity results of the asserted and/or challenged claims are properties of the formulation taught by the Label and therefore were inherently disclosed in this reference.

386. Such specific stability and impurity results also confirm that the formulation disclosed in the April 2014 Vasostrict® Label comprised a plurality of peptides, another feature inherent in the disclosure of this prior art reference. Finally, these results were obtained using the recited HPLC method and thus that element is also inherently disclosed in the description of the drug product.

387. Also as described in detail above, the April 2014 Vasostrict® Label also disclosed additional formulation elements of the asserted and/or challenged claims, including a formulation that is neither lyophilized nor frozen.

388. Finally, to the extent that Par asserts that Eagle's proposed ANDA labeling instructs in accordance with the "discard" limitation for handling, the April 2014 Vasostrict® Label contained the same instruction. *See, e.g.*, § 16. Further, as found by the examiner during prosecution and discussed in detail above, it would have been obvious to refrigerate prior art vasopressin compositions like the April 2014 Vasostrict® Label prior to administration.

389. I note that Par has, in this litigation, accused Eagle's ANDA product of infringing the claims of the '526, '209, '239, and '785 patents. As set forth above, Eagle's product [REDACTED]

[REDACTED]

[REDACTED]

In addition, I understand that all of the instructions in Eagle's proposed label cited by Par in alleging infringement, save for a slightly different refrigerated storage instruction, are found in the April 2014 Vasostrict® Label. Therefore, to the extent that Eagle's proposed ANDA product and

labeling infringes the claims of the asserted and/or challenged patents, then the April 2014 Vasostrict® Label must anticipate those claims.

a. '239 Patent

390. The examiner found that this Label rendered all pending claims of the '239 patent invalid for anticipation—as well as obviousness—during prosecution. As I have discussed, the applicants ultimately only distinguished the remaining cited prior art, primarily PPC, based on an alleged showing of criticality of the claimed pH range of 3.5 to 4.1 over the prior art range of 2.5 to 4.5. The pH range of 3.4 to 3.6 in the Label, however, would have anticipated the broad range of the '239 patent claims as issued. This Label would therefore have anticipated the claims of the '239 patent because it discloses each and every element of each and every claim, either expressly or inherently: the chemical composition of the unit dosage form, a narrower pH, the degradation products, discard time (if Eagle's labeling is alleged to instruct infringement), and the method of treating hypotension, as set forth by Dr. Cross. Had it been properly considered before the patent office, the claims of the '239 patent would not have issued. The April 2014 Vasostrict® Label is thus material to the patentability of the '239 patent.

b. '526, '209, and '785 Patents

391. As set forth above, the April 2014 Vasostrict® Label discloses or, in the case of refrigeration, renders obvious, the limitations of the '526, '209, and '785 patents, including with respect to the recited chemical composition of the unit dosage form, degradation and impurity levels, storage conditions, HPLC method, and the method of treating hypotension, as set forth by Dr. Cross.

392. Despite the different pH limitations of the '526, '209, and '785 patents, the April 2014 Vasostrict® Label and its pH range of 3.4 to 3.6 still render the asserted claims of these patents obvious. Given that the range of 3.4 to 3.6 is abutting (for the '209 and '785 patents) or

otherwise very close ('526 patent) to the recited pH, a POSA would have expected these compositions all to have similar properties. Although pH-dependent stability could change over even narrow ranges, the differences are typically small when looking at such ranges. Based on both my own review and Dr. Chyall's analysis, the basic stability studies conducted by Par confirm that formulations pH 3.4 to 3.6 do indeed behave similarly to the abutting recited values.

393. Given that these pH values result in similar stability, the applicants would not have been able to show criticality over the pH range of the April 2014 Vasostrict® Label. I understand from Dr. Chyall's opinion, based on his analysis of the pH data before the patent office and the experiments used to generate those data, that there is no indication that the particular claimed values led to any unexpected increase in stability relative to the pH range of the April Vasostrict® 2014 Label.

394. I also understand from Dr. Chyall's analysis, and agree, that the testing presented by the applicants during prosecution could not have shown criticality over the formulation set forth in the April 2014 Vasostrict® Label. That Label described a complete composition that had been developed by Par, with a shelf life of 12 months for which Par had extensive stability data. Showing criticality over that formulation would have required testing the claimed formulations against that prior art formulation, when instead the inventors tested a different formulation comprising just acetate buffer (which was not a component of the formulation in the April 2014 Vasostrict® Label) and vasopressin. It also would have required testing for the full shelf life set forth in the label and comparison with Par's own stability data, rather than just four weeks with contrived data.

395. Furthermore, consistent with my analysis set forth above for obviousness, a POSA would have found the optimization of pH around the range of the April 2014 Vasostrict® Label to

[REDACTED]

be routine. pH optimization of a peptide formulation is a routine process in the field of pharmaceutical dosage form design and development that is fundamental to the entire endeavor. When formulating vasopressin, a POSA would have looked to this range—the pH value used for an FDA-reviewed and FDA-approved drug product—for guidance and focused on testing pH values within and surrounding this range. These standard analyses would have rapidly revealed the optimum range or value—if any—and led a POSA to use the recited values, to the extent they truly are more stable.

396. Beyond the lack of data establishing criticality over this pH range from the April 2014 Vasostrict® Label, there is no indication that there is any benefit to the formulations and pH values of the asserted claims of the '526, '209, and '785 patents. Though the inventors claimed in declarations to the patent office that the formulations of these patents had lower impurity values relative to formulations with different pHs within the 2.5-4.5 range including those with pHs of 3.4-3.6, they [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] *See, e.g.,* Kannan Dep. 187:22–188:22; Vandse Dep. 254:16–22; Sanghvi Dep. 146:21–147:5, 148:14–149:8, 150:13–18, 151:3–22.

397. Given that the April 2014 Vasostrict® Label describes an actual formulation of vasopressin that was offered for sale by Par, there are also a number of FDA findings and representations that refute any alleged criticality of the asserted claims relative to the April 2014 Vasostrict® Label. When seeking approval for NDA 204485 on the original Vasostrict® product, Par represented to the FDA that:

[REDACTED]

[REDACTED]

PAR-VASO_0072478. This means that the prior art Vasostrict® formulation described in the April 2014 Vasostrict® Label was already optimized for the stability of vasopressin. And though Par removed the original Vasostrict® product from the market with the launch of the reformulated Vasostrict® product it now contends is covered by the asserted claims of the '526, '209, and '785 patents, the FDA has expressly “determined that the original formulation of Vasostrict, 20 units per mL, was not discontinued from sale for reasons of safety or effectiveness.” *E.g.*, [https://www.regulations.gov/contentStreamer?documentId=FDA-2017-P-1096-](https://www.regulations.gov/contentStreamer?documentId=FDA-2017-P-1096-0004&attachmentNumber=1&contentType=pdf)

[0004&attachmentNumber=1&contentType=pdf](https://www.regulations.gov/contentStreamer?documentId=FDA-2017-P-1096-0004&attachmentNumber=1&contentType=pdf). Like the inventors, the FDA could also not determine any detrimental property of original Vasostrict® or material benefit in safety or effectiveness for the formulations of the asserted claims. Indeed, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] *See, e.g.*, PAR-VASO_0093671; [Vandse Dep. Tr. 235:7–237:12; Kannan Dep. Tr. 176:11–17, 177:14–20, 305:8–306:10.

398. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

399. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

401. The patents themselves also indicate that claimed pH values of the '526, '209, and '785 patents are not critical over the April 2014 Vasostrict® Label. For example, each patent contains Examples, which, as confirmed by inventor Suketu Sanghvi, Sanghvi Dep. 203:25–205:4, describe the composition of original Vasostrict®, including its pH, and its use, as set forth in the April 2014 Vasostrict® Label, as an “[i]llustrative vasopressin formulation for clinical use.” *E.g.*, PAR-VASO-0000087–88. This suggests that the original Vasostrict® formulation and its pH of 3.4 to 3.6 was suitable for treating patients and, therefore, sufficiently stable for safety and efficacy. In addition, Examples 9 and 10 of these patents state that “[a]t 25° C., pH 3.7 provided the highest stability for vasopressin (Fig. 11),” while “[a]t 40° C., pH 3.6 provided the highest stability for vasopressin.” *E.g.*, PAR-VASO-0000106. This indicates that vasopressin has similar stability across the range from the range of the April 2014 Vasostrict® Label through the claimed values and thus these claimed values are not critical.

402. I also note that Par and the inventors have, at various points, claimed that a pH range of 3.5 to 4.1, a range of pH of 3.7 to 3.9, and a pH of 3.8 are each critical to the stability of vasopressin formulations relative to the range of 2.5 to 4.5 in PPC. This however, is illogical as it

would require showing that each successively narrower claim had unexpectedly superior stability over the broader range. However, at each step, the broader range would also be within the prior art. Par's own conclusions regarding, for example, the criticality of pH 3.5–3.6 (the very range of the April 2014 Vasostrict® Label) as part of the range of the '239 patent claims thus apply to the prior art that is considered for the claims of the '526, '209, and '785 patents.

403. Because the elements of the asserted claims of the '526, '209, and '785 patents are expressly or inherently disclosed in this Label, save for pH, the Label would have rendered the claims of the '526, '209, and '785 patents invalid as obvious had this reference been before the patent office, particularly because the pH values of these claims are not critical over the April 2014 Vasostrict® Label. The April 2014 Vasostrict® Label is therefore material to the patentability of the '526, '209, and '785 patents.

2. The April 2014 Vasostrict® Label Is the Closest Prior Art to the Asserted and/or Challenged Claims

404. In addition, it is my opinion that the April 2014 Vasostrict® Label is the closest prior art to the challenged claims of the '526, '209, '239, and '785 patents.

405. Unlike the PPC reference, among others, cited by the examiner, the April 2014 Vasostrict® Label discloses each and every limitation of the challenged claims of the '239 patent in a single reference and therefore anticipates those claims. Regarding pH, there would have been no need to consider whether the claims of the '239 patent recite a pH range that is critical because the April 2014 Vasostrict® Label teaches an anticipating range.

406. For the '526, '209, and '785 patents, the April 2014 Vasostrict® Label discloses a pH range that abuts or is much closer to the claimed pH ranges than the PPC range of 2.5 to 4.5. Indeed, as set forth above, the patents themselves reproduce material from the April 2014 Vasostrict® Label as part of their disclosures, including the particular pH range of that

formulation. At most, the lower end of the April 2014 Vasostrict® Label is just 0.4 pH units away from the claims of the '526 patent, while the PPC reference included pH values some 1.3 units away. Thus, the April 2014 Vasostrict® Label would have focused a POSA more specifically on the specific claimed values for optimization and is therefore a closer prior art reference.

407. In addition, the PPC reference did not disclose the clinical elements of the claims because it carries different indications and instructions for use. The April 2014 Vasostrict® Label, however, as set forth in Dr. Cross's report, disclosed each of the clinical elements exactly. To the extent met by Eagle's ANDA product labeling, the April 2014 Vasostrict® Label also disclosed additional handling steps, like the discard limitation, that are not in PPC.

408. Finally, although the examiner found that another prior art reference, Treschan, taught many of the clinical elements, they needed to be combined with other prior art to meet the claims, including the clinical elements. As stated in Dr. Cross's report, the April 2014 Vasostrict® Label disclosed those clinical elements essentially verbatim. In addition, the disclosures of the additional dilution references—Russell, Young, and Buck—cited for those method steps were also obviated by the disclosure of the April 2014 Vasostrict® Label, as noted by Dr. Cross. And unlike those references, the April 2014 Vasostrict® Label taught the specific components for the composition of vasopressin, not just the method of using it.

B. Pitressin® Properties

409. I understand that key properties of Pitressin®, including its target pH as well as the pH of many specific lots with values above that target range, were not disclosed to the patent office during prosecution of the challenged patents. This information is material to patentability and is closer prior art than the PPC reference over which the inventors argued criticality before the patent office.

[REDACTED]

410. I understand that [REDACTED]

[REDACTED]

[REDACTED] *See, e.g.,* Kenney Dep. Tr. at 14:12–25; Sanghvi 30(b)(6) Dep. Tr. 56:15–22; Kannan Dep. Tr. 47:3–10.

411. In addition, I understand that [REDACTED]

[REDACTED] *See, e.g.,* PAR-VASO_0088551. [REDACTED]

[REDACTED] PAR-VASO_0088569. [REDACTED]

[REDACTED] Par's Resp. Eagle's Req. Admis. No. 75.

1. The Properties of Pitressin® Are Material

412. As set forth above, the sales of Pitressin®, including [REDACTED] in particular, invalidate each and every claim of the asserted and or challenged claims. Considering the higher pH levels of many Pitressin® batches that were sold prior to the filing of the asserted and/or challenged claims, all of the composition limitations were in the prior art.

413. In addition, as set forth above, Par's allegations against [REDACTED] product necessarily imply that Pitressin® must also meet the limitations of the asserted and/or challenged claims. [REDACTED]

[REDACTED] *See, e.g.,* EAGLEVAS0000076. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

414. Furthermore, I understand from Dr. Cross that Pitressin® was in fact used to practice the claimed clinical elements—as largely admitted by Par—and the examiner expressly found that the clinical elements were in the cited prior art and would have been obvious to use with such formulation prior art. Pitressin® as sold with the aforementioned properties was therefore in public use to practice the claimed invention and/or could be combined with the clear disclosures of the clinical prior art. Thus, the full scope of each and every asserted and/or challenged claim of the patents would be within the prior art if the full range of Pitressin® properties were disclosed.

415. In addition, to the extent the target pH range of Pitressin®—[REDACTED]—or the pH of [REDACTED] are considered alone, the pH values of the asserted and/or challenged claims would still be invalid. Foremost, the pH of [REDACTED] is within that of the '239, '209, and '785 patents and is therefore anticipatory. In addition, for the '526 patent, the inventors would not have been able to show criticality of pH 3.8 over [REDACTED] for the same reasons discussed above for the April 2014 Vasostrict® Label. Even for [REDACTED] the inventors would have been unable to show criticality also for the same reasons above, as this is the same range as the April 2014 Vasostrict® Label.

416. Therefore, if the full properties of those prior art products that were on sale had been before the patent office, the claims of the '526, '239, '209, and '785 patents would not have issued. The withheld information regarding Pitressin® and [REDACTED] was therefore material to the patentability of the '526, '239, '209, and '785 patents.

2. Pitressin® Is Closer Prior Art

417. Because Pitressin® was formulated with a target pH of [REDACTED] it is closer prior art to the claims of the '526, '209, '239, and '785 patents than PPC for the same reasons as for the April 2014 Vasostrict® Label.

418. Furthermore, because Pitressin® [REDACTED] [REDACTED] it is closer prior art to the claims of the '526 patent because such sales disclose overlapping, i.e., anticipating, or abutting pH values. [REDACTED] [REDACTED] Therefore, Pitressin® is also closer prior art than PPC based on pH for the same reasons as set forth above for April 2014 Vasostrict® Label.

419. Furthermore, Pitressin® was, by Par's own admission, actually used to practice the methods of treatment. As stated above, PPC carried a different indication and, while vasopressin was, per Dr. Cross, widely used to practice the claimed methods, I have not seen any specific evidence that the PPC product was used in such a way. Nor would information about the use of PPC necessarily have been available to the inventors, unlike that of Pitressin® which was sold by the inventors' employer Par. Therefore, the properties of Pitressin®, combined with this use is closer prior art than PPC. By the same token, Pitressin® and its use are closer prior art than the clinical prior art cited by the examiner and analyzed by Dr. Cross, because those references do not appear to describe the actual compositions, unlike the disclosing sales of Pitressin®.

C. Vasostrict®

420. As set forth above, [REDACTED] [REDACTED]³⁵ PAR-VASO_0088587-88; PAR-VASO_0088551. Thus, although original Vasostrict® was formulated to a target pH of 3.4 to 3.6, [REDACTED] [REDACTED] See, e.g., PAR-VASO_0088587-88; PAR-VASO_0088551; September 2014 Vasostrict® Label § 16. [REDACTED] [REDACTED]

³⁵ As explained above, this result was recorded for

[REDACTED]

421. [REDACTED]

[REDACTED]

[REDACTED] *See, e.g.,* PAR-VASO_0088587–88; PAR-VASO_0088551. [REDACTED]

[REDACTED]

[REDACTED] *See, e.g.,* PAR-VASO_0088587–88.

422. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

423. As set forth above, [REDACTED]

[REDACTED] Par, however, has alleged infringement of the asserted and/or challenged claims in this litigation based [REDACTED]

[REDACTED] Under this interpretation, however, as stated, original Vasostrict® would also meet the pH limitations of each of the asserted and/or challenged claims.

424. As set forth above, original Vasostrict® satisfies the other composition elements of the claims and its labeling, according to Dr. Cross, disclosed each and every clinical element of the claims. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Because the examiner would have invalidated the claims based on the full properties of original Vasostrict®, this information is material to patentability.

425. Based on my review of the prosecution histories of the asserted and/or challenged patents, it is my opinion that this data and information regarding original Vasostrict® are highly material because they show that the prior art Vasostrict® product had the allegedly inventive pH of the asserted and/or challenged claims, at least according to Par's interpretation of the claims relied on to accuse Eagle's ANDA product of infringement.

426. Based on my review, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

427. Based on my review, I understand that the inventors never corrected the record to inform the patent office of the properties of the original Vasostrict®, including that its pH rose to 3.8 during storage, and that the relevant data in the patent specifications actually described the prior art.

428. To my knowledge and based on my review, the inventors have provided no explanation for why this information was withheld from the patent office.

D. Information Concerning pH Testing

429. As set forth above, the claims of the '526, '239, '209, and '785 patents issued only because of arguments the inventors made regarding pH and criticality over the prior art.

[REDACTED]

430. I understand that the inventors withheld normalized impurity data for their pH-dependent stability testing as well as information regarding the variability of their stability studies and prior pH-dependent stability analyses and conclusions.

431. I rely on Dr. Chyall's opinion that normalized impurity data, variability of their stability studies, and the prior pH-dependent stability analyses and conclusions that were withheld would have contradicted the inventors' criticality arguments and would have precluded any finding of criticality for the claimed pH values.

432. Because all other elements of the asserted and/or challenged claims were in the prior art—as found by the examiner and set forth in detail above—and the alleged criticality of the pH elements was the only reason the claims issued, if the withheld information had been before the patent office, the claims of the '526, '239, '209, and '785 patents would not have issued. The criticality arguments negated by the withheld information are the sole reason these claims issued, so if the Examiner had the withheld information about the inventors' experiments, the asserted and/or challenged claims would not have been allowed by the patent office.

433. [REDACTED]

[REDACTED] was therefore material to the patentability of the '526, '239, '209, and '785 patents.

434. [REDACTED]

[REDACTED]

according to Dr. Cross on whose opinion I rely, Vasostrict® in view of this pH data is closer prior art to the asserted and/or challenged claims than PPC for similar reasons as discussed above for April 2014 Vasostrict® Label and Pitressin®.



Dated: November 15, 2019

A handwritten signature in cursive script that reads "Kinam Park".

Kinam Park, Ph.D.

EXHIBIT A

CURRICULUM VITA

KINAM PARK

Purdue University
Weldon School of Biomedical Engineering

[REDACTED]
[REDACTED]
E-mail: kpark@purdue.edu
kinam.com; kinampark.com

October 2019

TITLE: Showalter Distinguished Professor of Biomedical Engineering
Professor of Pharmaceutics

Education: B.S. in Pharmacy 1971-1975 Seoul National University, Seoul, Korea
Ph.D. in Pharmaceutics 1979-1983 University of Wisconsin, Madison, WI
Postdoc in Chem. Eng. 1983-1985 University of Wisconsin, Madison, WI

Academic Appointment

7/06 - present	Showalter Distinguished Professor of Biomedical Engineering Purdue University
6/01 - present	President, Akina, Inc.
7/98 - present	Professor, Department of Biomedical Engineering, Purdue University
7/94 - present	Professor, Department of Pharmaceutics, Purdue University
7/90 - 6/94	Associate Professor, Department of Pharmaceutics, Purdue University
2/86 - 6/90	Assistant Professor, Department of Pharmaceutics, Purdue University
5/85 - 1/86	Research Assistant Professor Department of Pharmaceutics, University of Utah
4/83 - 4/85	Postdoctoral Research Associate Department of Chemical Engineering, University of Wisconsin
1/79 - 3/83	Research Assistant Department of Pharmaceutics, University of Wisconsin
3/75 - 7/77	Served in the Korean Army as a lieutenant

Awards and Honors

NIH New Investigator Research Award (1986)
Achievement Award in 1989 IBM Supercomputing Competition (1990)
Young Investigator Award: Controlled Release Society (1992)
Controlled Release Society-Merck Award for the Outstanding Paper in the Ag/Vet field (1997)
University Faculty Scholar, Purdue University (1999)
Clemson Award (the basic research category) of Society for Biomaterials (2001)
Research Achievement Award (Pharmaceutics and Drug Delivery Section) (2001)
Controlled Release Society-NanoSystems Outstanding Pharmaceutical Paper Award (2004)
Controlled Release Society Founders Award (2004)
Louis W. Busse Lectureship of School of Pharmacy, University of Wisconsin (2008)
Sigma Xi Research Award (the Purdue University Chapter) (2009)
Advisory Professor for Medical Science Research at Kyungpook National University (2009-2012)
The Nagai Foundation Tokyo Distinguished Lectureship (2010)
Purdue Cancer Research Award by Lafayette Lions Club (with Professor Ji-Xi Cheng) (2011)
Kyung Hee University International Scholar (2012)
Visiting Professor of Heilongjiang University of Chinese Medicine, China (2012)
Visiting Professor of Ajou University, Korea (2013)
Thomson Reuters' list of "The World's Most Influential Scientific Minds. 2014 (2014)
Korean-American Society in Biotech and Pharmaceuticals (KASBP)-Daewoong Award (2014)
Featured in Indiana at 200. A Celebration of the Hoosier State (2015)
Ashland Inc. Distinguished Lecturer at the University of Kentucky (2015)
Controlled Release Society Distinguished Service Award (2015)
Willis A. Tacker Prize for Outstanding Teaching in Weldon School of Biomedical Engineering (2015)
The 2015 Purdue Innovator Hall of Fame Inductee (2015)
Distinguished Scholar, the Chinese University of Hong Kong (2016)
Special Government Employee at FDA CDER (2016)
Clarivate Analytics' list of "Most Influential Scientific Minds. Highly Cited Researchers (2016)
Clarivate Analytics' list of "Highly Cited Researchers (2017)
The University of Auckland Distinguished Visitor Award (2017)
Clarivate Analytics' list of "Highly Cited Researchers (2018)
The 2018 CRS Foundation Award (honoring Kinam Park with Student Travel Grant Program) (2018)

Controlled Release Society-3M Drug Delivery Systems Graduate Student Outstanding Research Award
in Drug Delivery (Yoon Yeo: Controlled Release Society, 2003)
AAPS Outstanding Graduate Student Research Award in Pharmaceutical Technologies
(Mentoring Yong Qiu: American Association of Pharmaceutical Scientists, 2003)
AAPS Outstanding Graduate Student Research Award in Pharmaceutical Technologies
(Mentoring Yoon Yeo: American Association of Pharmaceutical Scientists, 2004)
Drug Delivery Special Interest Group Outstanding Contribution to the Society for Biomaterials
(Eunah Kang: Society for Biomaterials 2007)

Board of Governors of the Controlled Release Society (1993-1996)
Fellow, American Association for Pharmaceutical Scientists (AAPS) (1993)
President of the Korean-American Pharmaceutical Scientists Association (1995-97)
Fellow, American Institute for Medical and Biological Engineering (1996)
Fellow, Biomaterials Science and Engineering of the Society for Biomaterials (2000)
President of the Controlled Release Society (2001-2002)
Fellow, Controlled Release Society (2010)

Professional Activities

Advisory Board

Advisory Board of the Molecular Modeling Conference (1994)
Advisory Panel on Polymeric Excipients, USP (1995-1999)
ACS Books Advisory Board (1997-2000)
Advisory Panel on Current Drugs (1997-1999)
Scientific Advisory Board, International Symposium on the Frontiers in Biomedical Polymers Applications (2000-2001)
Scientific Advisory Board, International Symposium on Recent Advances in Drug Delivery Systems (2000-2001)
Advisory Panel on Excipients: Substance and Characterization Expert Committee, USP (2000-2005)
Scientific Program Committee of the 2nd Pharmaceutical Sciences World Congress (PSWC) (2004)
Scientific Advisory Board, Delsite, Inc. (2004-2008)
Scientific Advisory Board, International Nanomedicine and Drug Delivery Symposium (2005-)
Scientific Advisory Board, Soleira Laboratories (2006-2008)
Scientific Advisory Board, Boston Scientific (2006-2008)
Scientific Advisory Board, Lohmann Therapie-Systeme AG (2006-2012)
Scientific Advisory Board, European Symposium on Controlled Drug Delivery (2006-2009)
Scientific Advisory Board, China International Pharmaceutical Technologies Conference 2007 (2006-2008)
Scientific Organizing Committee for Micro 2007, the 16th International Symposium on Microencapsulation (2007)
International Advisory Board, CIMTEC 2008 the 3rd International Conference on Smart Materials, Structures and Systems (2007-2008)
Dean's Faculty Advisory Committee, Purdue University, College of Engineering (2007-2013)
Engineering Named Professorships Committee, Purdue University, College of Engineering (2007-2014)
Provost Search Committee, Purdue University (2007-2008)
Board of Directors & Chairman of Fellowship Committee, CRS Foundation (2008-2013)
International Advisory Board, CIMTEC 2010 the 5th Forum on New Materials & 9th International Conference on Medical Applications of Novel Biomaterials and Nano-biotechnology (2009-2012)
Drug Delivery Scientific Advisory Board, Genentech (2010-2015)
The International Symposium on Biomaterials and the China-Japan-Korea (Asia 3) Foresight Joint Symposium on Gene Delivery, Guilin, Guangxi, China (2010-2011)
Chairman, Dean's Faculty Advisory Committee, Purdue University, College of Engineering (2010-2012)
International Scientific Advisory Board, School of Pharmacy at Queen's University Belfast (2011)
Scientific Committee, the 19th International Symposium on Microencapsulation, Pamplona, Spain (2012-2013).
International Advisory Board, 20th International Symposium on Microencapsulation. IMS2015 Boston (2014)
External Advisor for the Center of Biological Research Excellence at the University of South Carolina (2014-2015)
Chair, the Annual Meeting Programme Committee for the Controlled Release Society conference in 2016.
Faculty Awards and Recognition (FAR) committee, College of Engineering representative (2015-2018)
Scientific Advisory Board, the International Conference on Biomaterials Science in Tokyo (2016)
International Advisory Board, CIMTEC 2018 the 8th Forum on New Materials & 12th International Conference on Medical Applications of Advanced Biomaterials and Nano-biotechnology (2017-2020)

External Advisor for Internal Projects at Korea Institute of Science and Technology (KIST) (2017)
International Organizing/Advisory Committee, 5th Symposium on Innovative Polymers for Controlled Delivery, Suzhou, China (2018)

Editorial Board

Journal of Biomaterials Science- Polymer Edition (1993-)
Journal of Bioactive and Compatible Polymers (1993-)
Journal of Controlled Release (1997-2005)
Colloids and Surfaces B: Biointerfaces (1997-)
Archives of Pharmacal Research (1998-)
PharmSci (official electronic journal of AAPS) (1999-2009)
PharmSciTech (official electronic journal of AAPS) (2001-2009)
Drug Delivery Technology (2002-)
Advanced Drug Delivery Reviews (2003-)
Biomaterials Research (2003-)
Encyclopedia of Pharmaceutical Technology (2003-)
Macromolecular Research (2004-)
Journal of Pharmacy and Pharmacology (2004-)
Journal of Biopharmaceutics and Biotechnology (2005-)
CRS Books (2006-)
Drugs in Pharmaceutical Sciences Series, Taylor & Francis & Informa (2007-)
Journal of Drug Delivery Science and Technology (2008-)
Nanomedicine: Nanotechnology, Biology and Medicine (2010-2011)
Nano Reviews (2010-)
Drug Delivery and Translational Research (2010-)
Frontiers in Drug Delivery Biotechnology (2010-)
Experimental Biology and Medicine (2012-2015)
Journal of Hydrogels (2013-)
Biomaterials Research (2014-)
Regenerative Engineering and Translational Medicine (2015-)
International Journal of Pharmaceutics (2018-)

Journal Editor

Associate Editor, Pharmaceutical Research (1995-2004)
Book Review Editor, Pharmaceutical Research (1996-2004)
Guest Editor, Colloids and Surfaces B: Biointerfaces (1998-1999)
Guest Editor, Advanced Drug Delivery Reviews (2001-2002)
Editor, Americas, Journal of Controlled Release (2005)
Editor-in-Chief, Journal of Controlled Release (2005-)

NIH Study Section

NIH Pharmacology Study Section member (1996-2001, 2003)
NIH Bioengineering, Technology, and Surgical Sciences Study Section member (2005-2009)
Member, College of CSR Reviewers, NIH (2010-2013, 2016)

Special Reviewer of NIH Study Sections

Surgery and Bioengineering Study Section (1991, 1995-1997, 1999, 2004)
Surgery, Anesthesiology, & Trauma Study Section (1992-1994)
Special Study Section SSS-8 (1995)
Pharmacology Special Study Section, Chairman (2001, 2002, 2003)
National Cancer Institute Special Emphasis Panel (2005)
Member of NIH SBIR Special Study Sections

Diabetes and Digestive and Kidney Diseases (1990, 1991, 1993), Pharmacology (1990, 1992, 1993), Physiological Sciences (1990), Reproductive Endocrinology (1990-1992, 1994-1996, 1999), Multidisciplinary Special Emphasis (1994, 1995), NIDDK (2009).

Membership in Academic, Professional, and Scholarly Societies

American Association of Pharmaceutical Scientists
 American Chemical Society
 Controlled Release Society
 Society for Biomaterials
 Biomedical Engineering Society

Books

- 1) Park, K., Shalaby, S.W.S., and Park, H.: *Biodegradable Hydrogels for Drug Delivery*, Technomic Publishing Co., Inc., Lancaster, PA, 1993, 252 pages.
- 2) Ottenbrite, R., Hwang, S., and Park, K., Eds.: *Hydrogels and Biodegradable Polymers for Bioapplications* (ACS Symposium Series 627), American Chemical Society, Washington, DC, 1996, 268 pages.
- 3) Park, K., Ed.: *Controlled Drug Delivery: Challenges and Strategies*, American Chemical Society, Washington, DC, 1997, 629 pages.
- 4) Park, K. and Mrsny, R., Eds.: *Controlled Drug Delivery: Designing Technologies for the Future* (ACS Symposium Series 752), American Chemical Society, Washington, DC, 2000, 459 pages.
- 5) Park, K.D., Kwon, I.C., Yui, N., Jeong, S.Y. and Park, K., Eds.: *Biomaterials and Drug Delivery toward New Millennium*, Han Rim Won Publishing Co., Seoul, Korea, 2000, 691 pages.
- 6) Yui, N., Mrsny, R., and Park, K., Eds.: *Reflexive polymers and hydrogels: Understanding and designing the fast-responsive polymeric systems*, CRC Press, Boca Raton, FL, 2004. 452 pages.
- 7) Morishita, M. and Park, K., Eds.: *Biodrug Delivery Systems: Fundamentals, Applications and Clinical Development*, (Volume 194 of the Drugs and the Pharmaceutical Sciences Series), Informa Healthcare, New York, NY, 2010. 471 pages.
- 8) Ottenbrite, R.M., Park, K., Okano, T., and Peppas, N.A., Eds.: *Hydrogels Handbook*, Springer, 2010, 432 pages.
- 9) Wen, H. and Park, K., Eds.: *Oral Controlled Release Formulation Design and Drug Delivery: Theory to Practice*, John Wiley & Sons, New York, NY, 2010. 363 pages.
- 10) Bae, Y.H., Mrsny, R., and Park, K., Eds.: *Cancer Targeted Drug Delivery: An Elusive Dream*, Springer, New York, 2013, 720 pages.
- 11) Park, K., Ed.: *Biomaterials for Cancer Therapeutics: Diagnosis, Prevention, and Therapy*, Woodhead Publishing Ltd., Oxford, UK, 2013, 528 pages.
- 12) Hillery, A. and Park, K., Eds.: *Drug Delivery: Fundamentals and Applications*, Second Edition, CRC Press/Taylor & Francis Group, Boca Raton, FL, 2016. ISBN: 978-1-4822-1771-1. 614 pages.
- 13) Park, K., Ed.: *Biomaterials for Cancer Therapeutics: Evolution and Innovation*, Elsevier., 2019, in press.

Journal Special Issues

- 1) Park, K. Ed., *Protein- and Cell-Repellent Surfaces*, Colloids and Surfaces B: Biointerfaces, Elsevier Science, Vol. 18 (No. 3-4), 2000. (with Editorial on p.167).

- 2) Park, K., Ed., *Recent Developments in Hydrogels*, Advanced Drug Delivery Reviews, Elsevier Science, Vol. 54 (1), 2002. (With Preface on p.1).

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- 1) Park, K. and Robinson, J.R.: Bioadhesive polymers as platforms for oral-controlled drug delivery: method to study bioadhesion, *Int. J. Pharm.* 19: 107-127, 1984.
- 2) Park, K. and Cooper, S.L.: Importance of composition of the initial protein layer and platelet spreading in acute surface-induced thrombosis, *Trans. Amer. Soc. Artif. Inter. Organs* 31: 483-488, 1985.
- 3) Park, K., Mosher, D.F., and Cooper, S.L.: Acute surface-induced thrombosis in the canine ex vivo model: Importance of protein composition of the initial monolayer and platelet activation, *J. Biomed. Mater. Res.* 20: 589-612, 1986.
- 4) Park, K., Albrecht, R.M., Simmons, S.R., and Cooper, S.L.: A new approach to study the adsorbed protein layer on biomaterials: Immunogold staining techniques, *J. Colloid Interf. Sci.* 111: 197-212, 1986.
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- 6) Pitt, W.G., Park, K., and Cooper, S.L.: Sequential protein adsorption on platelet deposition on polymer surfaces, *J. Colloid Interf. Sci.* 111: 343-362, 1986.
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- 9) Pitt, W.G., Young, B.R., Park, K., and Cooper, S.L.: Plasma protein adsorption: in vitro and ex vivo observations. *Makromol. Chem., Macromol. Symp.*, 17: 453-465, 1988.
- 10) Park, K.: Enzyme-digestible swelling hydrogels as platforms for long-term oral drug delivery: synthesis and characterization. *Biomaterials*, 9: 435-441, 1988.
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- 13) Park, K. and Park, H.: Application of video-enhanced interference reflection microscopy to the study of platelet-surface interactions, *Scanning Microscopy*, Suppl. 3: 137-146, 1989.
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- 15) Park, K., Mao, F. W., and Park, H.: Morphological characterization of surface-induced platelet activation, *Biomaterials*, 11:24-31, 1990.
- 16) Shalaby, W.S.W. and Park, K.: Biochemical and mechanical characterization of enzyme-digestible hydrogels, *Pharm. Res.*, 7:816-823, 1990.
- 17) Lu, D.R. and Park, K.: Protein adsorption on polymer surfaces: calculation of adsorption energies, *J. Biomater. Sci. Polymer Edn.*, 1:243-260, 1990.
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- 19) Park, K., Mao, F. W., and Park, H.: The minimum surface fibrinogen concentration necessary for platelet activation on dimethyldichlorosilane-coated glass, *J. Biomed. Mater. Res.*, 25: 407-420, 1991.
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- 7) Huh, K.M., Cho, Y.W., and Park, K.: PLGA-PEG block copolymers for drug formulations, *Drug Delivery Technology*, 3(5): 52-58, 2003.
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- 9) Leaming, M. and Park, K.: Journal of Controlled Release Highlights, *Controlled Release Society Newsletter*, 22 (3), 27, 2005.
- 10) Leaming, M. and Park, K.: Journal of Controlled Release Highlights, *Controlled Release Society Newsletter*, 23 (1), 15, 2006.
- 11) Leaming, M. and Park, K.: Journal of Controlled Release Highlights, *Controlled Release Society Newsletter*, 23 (2), 12, 2006.
- 12) Park, K.: Journal of Controlled Release Highlights, *Controlled Release Society Newsletter*, 24 (3), 5, 2007.
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Invited Lectures

- 1) Surface characterization of biomaterials by immunogold staining. Scanning Electron Microscopy 1986, Biotechnology and Bioapplication of Colloidal Gold, New Orleans, LA, May 5-9, 1986.
- 2) Platelet behavior at polymer-blood interfaces. Devices and Technology Branch Contractors Meeting, Bethesda, MD, Dec. 8-10, 1986.
- 3) Enzyme-digestible hydrogels - new platforms for oral controlled drug delivery, INTERx Research Corporation, Lawrence, KS, October 12, 1987.
- 4) Factors affecting efficiency of colloidal gold staining colloidal stability, The 7th Pfefferkorn Conference on Science of Biological Specimen Preparation, Guildford, England, September 12-16, 1988.
- 5) Examination of cytoskeletal structures of spread platelets using video-enhanced interference reflection microscopy, *The 7th Pfefferkorn Conference on Science of Biological Specimen Preparation*, Guildford, England, September 12-16, 1988.
- 6) Time-lapse video microscopic analysis of surface-induced platelet activation, Conference on Platelet Structure and Adhesion, Madison, WI, October 27-28, 1988.
- 7) New approach to study bioadhesion: colloidal gold staining, AMGEN, Thousand Oaks, CA, November 11, 1988.
- 8) The redistribution of fibrinogen receptors on the ventral membrane of spreading platelets, Scanning Microscopy 1989, Colloidal Gold Labelling, Salt Lake City, UT, May 1-5, 1989.
- 9) Drug delivery systems using enzyme-digestible swelling/mucoadhesive hydrogels, The Fall Workshop of the Korean Federation of Science and Technology Societies, Seoul, Korea, October 11-13, 1989.
- 10) Modification of surface-adsorbed fibrinogen by spreading platelets, Third Annual Midwest Platelet Symposium, Madison, WI, November 17, 1989.

- 11) A new approach to study mucoadhesion: Colloidal gold staining, Center for Controlled Chemical Delivery, Salt Lake City, UT, January 30, 1990.
- 12) New approaches to the study of polymer-mucin interactions, Gordon Research Conferences on Polymers in Biosystems, Oxnard, CA, March 19-23, 1990.
- 13) Prevention of platelet adhesion and activation by surface modification, Shiley Incorporated, Irvine, CA, May 9, 1990.
- 14) Biodegradable hydrogels as platforms for long-term oral drug delivery, Fourth Annual Symposium of the Johnson & Johnson Drug Delivery Subcommittee, October 8, 1990.
- 15) In vitro and in vivo studies of enzyme-digestible hydrogels for oral drug delivery, Fifth International Symposium on Recent Advances in Drug Delivery Systems, Salt Lake City, UT, February 25-28, 1991.
- 16) Application of quantitative colloidal gold staining to the study of mucin-polymer interactions, Scanning '91, Atlantic City, NJ, April 10-12, 1991.
- 17) Development of long-term oral drug delivery systems using enzyme-digestible swelling hydrogels, Syntex Research, Palo Alto, CA, June 10, 1991.
- 18) Application of quantitative colloidal gold staining to the study of mucin-polymer interactions, 3M Life Sciences Sector, St. Paul, MN, June 13, 1991.
- 19) Prevention of platelet adhesion and activation by surface modification, 3M Life Sciences Sector, St. Paul, MN, June 14, 1991.
- 20) Hydrogel systems, 204th ACS National Meeting, Washington, D.C., August 23, 1992.
- 21) Hydrogel systems in pharmaceuticals, 1992 Annual Meeting of AAPS, PDD Symposium on Polymer Science: Unique Applications in the Pharmaceutical Industry, San Antonio, TX, November 17, 1992.
- 22) Oral vaccination using hydrogels, Miles Inc., Animal Health Products, Shawnee Mission, KS, February 24, 1993.
- 23) Biodegradable hydrogels for delivery of protein drugs, The 205th American Chemical Society National Meeting, Division of Polymer Chemistry, Denver, CO, April 1, 1993.
- 24) Evaluation of bioadhesion by colloidal gold staining, Gliatech, Inc., Cleveland, OH, June 11, 1993.
- 25) Surface modification of biomaterials, Korea Institute of Science & Technology, Seoul, Korea, June 25, 1993.
- 26) Prevention of protein adsorption and cell adhesion, Gordon Conference on Biocompatibility and Biomaterials, Tilton, NH, July 11, 1993.
- 27) Smart hydrogels for pharmaceutical applications, PharmTech Conference, Atlantic City, NJ, September 22, 1993.
- 28) Protein interactions with surfaces, American Vacuum Society, Orlando, FL, November 15, 1993.
- 28) New methods for modification of polymeric biomaterials, BSI Corporation, Eden Prairie, MN, November 5, 1993.
- 29) Protein interactions with surfaces, American Vacuum Society, Orlando, FL, November 15, 1993.
- 30) Surface modification of biomaterials, Cedars-Sinai Medical Center, Los Angeles, CA, November 22, 1993.
- 31) Smart hydrogels, WCCR Literature Meeting, Purdue University, West Lafayette, IN, April 22, 1994.
- 32) Polysaccharide hydrogels for controlled drug delivery, Frontiers in Carbohydrate Research Conference, West Lafayette, IN, May 10, 1994.

- 33) Surface modification for prevention of protein adsorption, AAPS Midwest Regional Meeting, Chicago, IL, May 23, 1994.
- 34) Oral vaccination of cattle via hydrogel delivery systems, The 21st International Symposium on Controlled Release of Bioactive Materials, Nice, France, June 27, 1994.
- 35) Surface modification of biomaterials for the prevention of protein adsorption and cell adhesion, Dept. of Biomedical Engineering, Duke University, Durham, NC, October 17, 1994.
- 36) Development of modulated insulin delivery systems: prospects and limitations, Korea Basic Science Center, Seoul, Korea, October 24, 1994.
- 37) Oral vaccination hydrogel systems, Second International Symposium on Biomaterials and Drug Delivery Systems, Korea Institute of Science and Technology, Seoul, Korea, October 25, 1994.
- 38) Recent advances in drug delivery systems using hydrogels, *Pacific Corporation*, Seoul, Korea, October, 28, 1994.
- 39) Surface modification of biomaterials, Center of Membrane Sciences, University of Kentucky, Lexington, KY, December 6, 1994.
- 40) Synthesis of novel sucrose-derived hydrogels and hydrogel foams for pharmaceutical applications, The Sugar Association, Washington, D.C., March 7, 1995.
- 41) Oral vaccination hydrogel systems, The Seventh International Symposium on Recent Advances in Drug Delivery Systems, Salt Lake City, UT, February 28, 1995.
- 42) Surface modification for the prevention of protein adsorption and cell adhesion, College of Pharmacy, University of Michigan, Ann Arbor, MI, March 8, 1995.
- 43) Stent regulation of the vascular microenvironment, The 41st Annual Conference of ASAIO (American Society for Artificial Internal Organs), Chicago, IL, May 6, 1995.
- 44) Synthesis of glucose-sensitive phase-reversible hydrogels, 11th International Symposium on Affinity Chromatography and Biological Recognition, San Antonio, TX, May 27, 1995.
- 45) Smart hydrogels for pharmaceutical applications, Strategies for new drug and vaccine development, 5th Annual Meeting of the Society of Biomedical Research, Washington, D.C., September 15, 1995.
- 46) Surface modification of biomaterials, EE520 Biomedical Engineering Seminar, Purdue University, October 31, 1995.
- 47) Recent trend in pharmaceutical research, Choongwae Pharmaceuticals, Seoul, Korea, December 12, 1995.
- 48) Controlled drug delivery using smart hydrogels, Choongwae Research Labs., Suwon, Korea, December 13, 1995.
- 49) Smart hydrogels, Collagen Corp., Palo Alto, CA, February 6, 1996.
- 50) Issues in the implantable drug delivery systems, 42nd Annual Conference of American Society for Artificial Internal Organs, Washington, D.C., May 3, 1996.
- 51) Controlled drug delivery: Present and future, The Madison Conference on the Pharmaceutical Sciences, 1996, Madison, WI, June 7, 1996.
- 52) Computer simulation in drug delivery and biomaterials research: Oral vaccination hydrogel systems, Third International Symposium on Biomaterials and Drug Delivery Systems, Korea Research Institutes of Chemical Technology, Taejeon, Korea, July 5, 1996.
- 53) Hydrogel foams, Korea Institute of Science & Technology, Seoul, Korea, August 13, 1996.

- 54) A view on future glucose sensors and insulin delivery systems, Cygnus Corp., Redwood City, CA, October 24, 1996.
- 55) Self-regulated insulin delivery and glucose sensing, Fukuoka University, Fukuoka, Japan, May 13, 1997.
- 56) Future of glucose sensing and insulin delivery: A point of view, The First Asian International Symposium on Polymeric Biomaterials Science, Ishikawa, Japan, May 15, 1997.
- 57) New and emerging polymers and hydrogels, Land of Lake Conference on Challenges and Prospects in the Design and Development of Oral Controlled Release Products, Merric, WI, June 4, 1997.
- 58) Biocompatibility of implantable drug delivery systems, CRS-CPA Joint Workshop on Recent Advances in Drug Delivery Science and Technology, Beijing, China, September 20, 1997.
- 59) Biocompatibility of biomaterials, KSP-CRS Joint Symposium on Recent Advances in Drug Delivery and Biomaterials, Seoul, Korea, September 26, 1997.
- 60) Protein adsorption on surfaces with grafted polymers- Experiment, The Purdue Industrial Associates Program on Chemistry of Materials, Purdue University, West Lafayette, IN, October 3, 1997.
- 61) How to respond to reviewers' critiques, The Education Committee sponsored program on How to Write a Research Article at the American Association of Pharmaceutical Scientists 12th National Meeting, Boston, MA, November 4, 1997.
- 62) Fractal analysis of pharmaceutical particles, University of Wisconsin, School of Pharmacy, Madison, WI, January 5, 1998.
- 63) Superporous hydrogel composites: A new class of hydrogels for biomedical and pharmaceutical applications, The Fifth European Symposium on Controlled Drug Delivery, Noordwijk aan Zee, The Netherlands, April 1-3, 1998.
- 64) Drug delivery technology: Use of novel polymers and hydrogels, The AAPS Midwest Regional Meeting, Chicago, IL, May 18, 1998.
- 65) Analysis of glucose-binding molecules, The 25th International Symposium on Controlled Release of Bioactive Materials, Las Vegas, NV, June 23, 1998.
- 66) AFM and fractal analysis of biomaterial microtopography, Microscopy & Microanalysis '98, Atlanta, GA, July 12-16, 1998.
- 67) Oral vaccination using microparticles: potentials and future directions, Pharmaceutical and Analytical & Development, Abbott Laboratories, Chicago, IL, July 24, 1998.
- 68) Surface-grafted PEO chains: Experiments, theoretical analysis, and computer simulation, Non-Fouling Surface Technologies Symposium, Seattle, WA, July 30-31, 1998.
- 69) Superporous hydrogels: Fast responsive hydrogel systems, The American Chemical Society National Meeting. PMSE and Polymer Chemistry Divisions, Boston, MA, August 21-26, 1998.
- 70) Superporous hydrogel composites: synthesis, characterization, and application, The American Chemical Society National Meeting. Polymer Chemistry Divisions, Boston, MA, August 21-26, 1998.
- 71) Fractal analysis of pharmaceutical particles, Korea Institute of Science and Technology, Seoul, Korea, November 10, 1998.
- 72) Superporous hydrogels: medical and pharmaceutical applications, Korea Advanced Institute of Science and Technology, Taejon, Korea, November 11, 1998.
- 73) Fractal analysis of pharmaceutical particles, Korea Research Institute of Chemical Technology, Taejon, Korea, November 11, 1998.

- 74) Development and evaluation of medical devices and materials, The Second International Symposium on Current Status of International Regulation on Food and Drug, Korea Food and Drug Administration, Seoul, Korea, November 13, 1998.
- 75) Superporous hydrogels: medical and pharmaceutical applications, University of Minnesota, Biomedical Engineering Center and Department of Pharmaceutics, Minneapolis, MN, December 3, 1998.
- 76) Hydrogels in drug delivery, Ninth International Symposium on Recent Advances in Drug Delivery Systems, Salt Lake City, UT, February 22, 1999.
- 77) Superporous hydrogels: pharmaceutical and medical applications, Yamanouchi Shaklee Pharma, Palo Alto, CA, March 19, 1999.
- 78) Video-enhanced interference reflection microscopy and video-intensified fluorescence microscopy, The Society for Biomaterials Academic Workshop on Probing and Imaging of Cells and Molecules, Providence, RI, April 28, 1999.
- 79) Degradable, fast-swelling, superporous sucrose hydrogels, Frontiers in Carbohydrate Research-6, West Lafayette, IN, May 12, 1999.
- 80) Characterization of morphological features of crystal surface during dissolution process, University of Utah, Salt Lake City, UT, May 17, 1999.
- 81) Superporous hydrogels: pharmaceutical and medical applications, Alza Corp., Palo Alto, CA, June 15, 1999.
- 82) Surface modified biomaterials: in vitro and in vivo behavior, UWEB Symposium on Devices and Diagnostics in Contact with Blood: Issues in Blood Compatibility at the Close of the 20th Century, Seattle, WA, August 4-6, 1999.
- 83) In vitro and in vivo behavior of surface modified biomaterials, KAIST, Taejon, Korea, August 28, 1999.
- 84) Superporous hydrogels: Synthesis and Application, The 5th International Symposium on Polymers for Advanced Technologies, Waseda University, Tokyo, Japan, August 31-September 5, 1999.
- 85) Pharmaceutical and biomedical applications of superporous hydrogels, Pusan National University, September 13, 1999.
- 86) Surface modified biomaterials: in vitro and in vivo behavior, KIST, Seoul, Korea, September 14, 1999.
- 87) Development of oral paclitaxel delivery systems, Sam Yang Corp., Taejon, Korea, September 17, 1999.
- 88) Pharmaceutical and biomedical applications of superporous hydrogels, Sook Myung Women's University, September 18, 1999.
- 89) Pharmaceutical and biomedical applications of superporous hydrogels, Dong Kook University, September 20, 1999.
- 90) Gastric retention drug delivery systems: Past and present, U.S. Food and Drug Administration, Rockville, MD, September 29, 1999.
- 91) Gastric retention drug delivery systems: Past and present, Kos Pharmaceutical, Edison, NJ, October 14, 1999.
- 92) Superporous hydrogels: pharmaceutical and medical applications, Ohio State University, Columbus, OH, October 28, 1999.

- 93) Superporous hydrogels: pharmaceutical and medical applications, Procter & Gamble Company, Cincinnati, OH, November 1, 1999.
- 94) Polymeric systems for oral controlled delivery, AAPS-Northeast Regional Discussion Group, Hartford, CT, April 24, 2000.
- 95) Modulated insulin delivery using glucose-sensitive sol-gel phase reversible hydrogels, Workshop on Supramolecular Approach to Biological Function, World Biomaterials Congress Workshop, Hawaii, May 15, 2000.
- 96) Superporous hydrogels for oral controlled drug delivery, Chong Kun Dang Corp., Seoul, Korea, May 18, 2000.
- 97) Superporous hydrogels for oral controlled drug delivery, Cheil Jedang Corp., Seoul, Korea, May 19, 2000.
- 98) Polymers in oral drug delivery, Kwang Ju Institute of Science and Technology, Kwang Ju, Korea, May 22, 2000.
- 99) Drug discovery in global economy, Korean Society of Pharmaceutics, Seoul, Korea, May 26, 2000.
- 100) PEO-grafted biomaterials: In vitro and in vivo behavior, Dept. of Chemical and Materials Engineering, University of Kentucky, Lexington, KY, June 30, 2000.
- 101) Modulated insulin delivery using phase-reversible glucose-sensitive hydrogels, The 40th Microsymposium of the Prague Meetings on Macromolecules, the International Union of Pure and Applied Chemistry, July 18, 2000.
- 102) Modulated insulin delivery using phase-reversible glucose-sensitive hydrogels, The 8th Hydrogel, Biodegradable Polymers for Medical Application Workshop, Korea Advanced Institute of Science and Technology, August 24, 2000.
- 103) PEG-modified biomaterials: Lack of in vitro-in vivo correlation, Univ. of Alabama in Huntsville, January 19, 2001.
- 104) Superporous hydrogels: pharmaceutical and biomedical applications, The North Carolina Pharmaceutical Discussion Group, Chapel Hill, NC, March 28, 2001.
- 105) Glucose-sensitive sol-gel reversible hydrogels for modulated insulin delivery, University of North Carolina, Chapel Hill, NC, March 29, 2001.
- 106) Gastric retention devices: Past and present, GlaxoWellcome, Chapel Hill, NC, March 30, 2001.
- 107) Superporous hydrogels for biomedical and pharmaceutical applications, Society for Biomaterials Annual Meeting, Minneapolis, MN, April 26, 2001.
- 108) Polymers in oral drug delivery, University of Maryland, Baltimore, MD, May 3, 2001.
- 109) Gastric retention drug delivery systems: Past and present, Northeastern University, Boston, MA, May 18, 2001.
- 110) Hydrotropic polymers for enhancing water solubility of poorly soluble drugs, The University of Tokyo, Tokyo, Japan, July 8, 2001.
- 111) Hydrotropic polymers for enhancing water solubility of poorly soluble drugs, Japan Advanced Institute of Science and Technology, Ishikawa, Japan, July 9, 2001.
- 112) Hydrotropic polymers for enhancing water solubility of poorly soluble drugs, Korea Institute of Science and Technology, Seoul, Korea, July 13, 2001.
- 113) Hydrotropic polymers for enhancing water solubility of poorly soluble drugs, Korea Research Institute of Chemical Technology, Taejeon, Korea, July 20, 2001.

- 114) Drug delivery, Biomaterials in 2001: State of the art. UWEB Summer Symposium, Seattle, WA, August 21, 2001.
- 115) Superporous hydrogels for pharmaceutical and biomedical applications, University of Georgia, College of Pharmacy, Athens, GA, Nov. 12, 2001.
- 116) Hydrotropic polymers and hydrogels for poorly soluble drugs, Samyang Corp., Taejeon, Korea, November 21, 2001.
- 117) Controlled drug delivery systems: Target areas for product development, Samyang Corp., Yongin-Si, Korea, November 22, 2001.
- 118) Hydrogels in pharmaceutical and biomedical applications, University of Southern California, Los Angeles, CA, December 7, 2001.
- 119) Hydrogels in drug delivery, University of Pennsylvania, Institute of Medicine and Engineering, Philadelphia, PA, January 29, 2002.
- 120) Hydrogels in controlled drug delivery, The 17th Annual Meeting of the Academy of Pharmaceutical Science and Technology, Japan (APSTJ), Shizuoka, Japan, March 30, 2002.
- 121) Polymeric systems in oral controlled drug delivery, Taisho Pharmaceutical Co., Ltd., Saitama-shi, Saitama, Japan, April 2, 2002.
- 122) Polymeric systems in oral controlled drug delivery, Daiichi Pharmaceutical Co., Ltd., Tokyo, Japan, April 2, 2002.
- 123) Hydrogels in drug delivery, AAPS/PDD Conference, Washington, D.C., April 22-24, 2002.
- 124) Novel hydrogels in drug delivery applications, University of Michigan, Ann Arbor, MI, May 15, 2002.
- 125) Hydrogels in drug delivery, University of Toronto, Toronto, Canada, May 30, 2002.
- 126) New platforms for drug delivery, McMaster University, Hamilton, Ontario, Canada, May 31, 2002.
- 127) Polymers and hydrogels in drug delivery: Design and applications, Inhale Therapeutic Systems, Inc., San Carlos, CA, June 12, 2002.
- 128) Novel hydrogels in drug delivery, UK/Ireland chapter of the Controlled Release Society (UKICRS) and 139th British Pharmaceutical Conference, Manchester, United Kingdom, September 24, 2002.
- 129) Nano-structures for delivery of poorly soluble drugs, Nano-biomaterials for drug, gene, and cell therapy, Korea Advanced Institute of Science and Technology, Taejeon, Korea, November 1, 2002.
- 130) New hydrogels for delivery of poorly soluble drugs and proteins, University of Illinois-Chicago, Chicago, IL, November 20, 2002.
- 131) Glucose imprints for modulated insulin delivery, Korean Chemical Society, Polymer Chemistry Division, Taejeon, Korea, December 13, 2002.
- 132) Solvent exchange method: A new process for making reservoir-type microcapsules, 11th International Symposium on Recent Advances in Drug Delivery Systems, Salt Lake City, UT, March 3, 2003.
- 133) Novel methods of making microcapsules based on the solvent exchange method, AAPS Conference on Advances in Pharmaceutical Processing, Parsippany, NJ, June 19, 2003.
- 134) Biomimetic materials, Controlled Release Society Annual Meeting, Glasgow, Scotland, July 22, 2003.
- 135) Solvent exchange method: A new process for making reservoir-type microcapsules, Northeastern University, Boston, MA. September 8, 2003.

- 136) Oral drug delivery: Scientific challenges vs. product development, Oral Drug Delivery Conference, Boston, MA, September 9, 2003.
- 137) Recent progresses in fast melting tablets and delivery of poorly soluble drugs, AAPS Chicago Pharmaceutics Discussion Group Meeting, Chicago, IL, October 9, 2003.
- 138) Hydrotropic polymeric micelle systems for formulation of poorly water-soluble drugs, The 8th European Symposium on Controlled Drug Delivery, Noordwijk aan Zee, The Netherlands, April 7-9, 2004.
- 139) Novel microencapsulation techniques based on the solvent exchange method, Pharmaceutical Sciences World Congress (PSWC2004), 2nd World Congress of the Board of Pharmaceutical Sciences of FIP, Kyoto, Japan, May 31, 2004.
- 140) Nanotechnology: Innovation or rebranding? Debate with Sandy Florence in Pearls of Wisdom, 31st Annual Meeting and Exposition of the Controlled Release Society, Honolulu, HI, June 16, 2004.
- 141) Hydrotropic polymer systems for poorly soluble drugs, 31st Annual Meeting and Exposition of the Controlled Release Society, Honolulu, HI, June 16, 2004.
- 142) Nanopolymeric structures for delivery of paclitaxel, School of Pharmacy, University of Kentucky, September 3, 2004.
- 143) Hydrotropic polymeric nanostructures for delivery of paclitaxel, Nanoparticles. Synthesis, Functionalization and Applications for Targeted Drug Delivery, Cleveland, OH, October 27, 2004.
- 144) Challenges and strategies in drug delivery from coronary stents, Biointerface 2004, Baltimore, MD, October 28, 2004.
- 145) Drug-eluting stents, Boston Scientific, Natick, MA, October 29, 2004.
- 146) Novel methods of making microcapsules based on the solvent exchange method. (Roundtable on Issues in Protein Microencapsulation), 2004 AAPS Annual Meeting, Baltimore, MD, November 10, 2004.
- 147) Recent advances in drug-eluting stents, Korea Research Institute of Chemical Technology, Taejeon, Korea, November 24, 2004.
- 148) Polymers in everyday life, LG Household & Healthcare, Taejeon, Korea, November 24, 2004.
- 149) Recent advances in drug-eluting stents, University of Utah, College of Pharmacy, January 5, 2005.
- 150) Preparation of PLGA microcapsules by the interfacial solvent exchange method, University of Pittsburgh, January 24, 2005.
- 151) Hydrotropic polymers for delivery of poorly soluble drugs, Inha University, Incheon, Korea, July 13, 2005.
- 152) Hydrotropic polymers for delivery of poorly soluble drugs, Boehringer-Ingelheim, Ridgebury, CT, July 20, 2005.
- 153) Oral drug delivery: Scientific challenges and product development, Annual Meeting of the Pharmaceutical Society of Korea, Seoul, Korea, November 29, 2005.
- 154) Polymers used in pharmaceutics, The 2006 AAPS PT Arden Conference, West Point, NY, January 25, 2006.
- 155) Polymer properties for controlled drug delivery, The 2006 AAPS PT Arden Conference, West Point, NY, January 25, 2006.
- 156) Nano/micro drug delivery systems and cellular uptakes, Symposium on Development of New Radiotherapy Technique Using Nano Drug Delivery System, Asan Medical Center, Seoul, Korea, March 10, 2006.

- 157) Controlled drug delivery: From macro to nanotechnologies, Institute of Genetics and Molecular Biology, Seoul National University, Seoul, Korea, June 23, 2006.
- 158) Drug delivery: Evolution into the nanotechnology era, Institute of Bioengineering and Nanotechnology, Republic of Singapore, July 3, 2006.
- 159) Novel methods for microsphere formulation and manufacture, The CMC and Regulatory Issues for Controlled Release Parenterals Workshop at the 33rd Annual Meeting of the Controlled Release Society, Vienna, Austria, July 29, 2006.
- 160) Label-free imaging tools for pharmaceutical and biomedical applications: CARS and SPR, Asan Medical Center, Seoul, Korea, September 5, 2006.
- 161) Nanomedicine: Evolution, revolution, and transformation, Mini Symposium on Molecular Imaging and Nanomedicine, Kyungbook National University, School of Medicine, Daegu, Korea, September 6, 2006.
- 162) Nanomedicine: Evolution, revolution, and transformation, 1st Purdue-KIST Collaborative Symposium on Biomedical Photonics, Korea Institute of Science and Technology, Seoul, Korea, September 7, 2006.
- 163) Translational research in drug delivery, LTS Academy, Andernach, Germany, October 6-8, 2006.
- 164) Imaging study of paclitaxel release from drug-eluting stents, University of Michigan, Ann Arbor, MI, October 19, 2006.
- 165) Nanotechnologies in drug delivery, NanoBio-Tokyo 2006, The University of Tokyo, December 4-7, 2006.
- 166) Fast-melting tablet formulations for controlled release and for large dose drugs, Astellas Pharma, Yaizu, Japan, December 7, 2006.
- 167) Drug-eluting stents: Imaging studies & strategies, Tokyo Women's Medical University Institute of Advanced Biomedical Engineering and Science, Tokyo, Japan, December 8, 2006.
- 168) Nanomedicine: Evolution, revolution, and transformation, The 2007 National Meeting of the Association for Laboratory Automation, Palm Springs, CA, January 27-31, 2007.
- 169) Scientific possibilities for combination products of the future, Symposium on Combination Products in Life Science Industries, Cook Inc. International Headquarters, Bloomington, IN, February 2, 2007.
- 170) Fast-melting tablet formulations for controlled release and for large dose drugs & fast-swelling hydrogels for biomedical applications, Abbott Laboratories, Abbott Park, IL, April 9, 2007.
- 171) Polymeric micelles for delivery of poorly soluble drugs & microcapsules for delivery of protein drugs, Abbott Laboratories, Abbott Park, IL, April 9, 2007.
- 172) What's wrong with the new drug delivery systems? CDER VPLS & ONDQA - cTiPS, USFDA, Rockville, MD, April 23, 2007.
- 173) Fast dissolving tablets - Current development and technologies, OGD, USFDA, Rockville, MD, April 23, 2007.
- 174) Overview of polymers used in controlled release, China International Pharmaceutical Technologies Conference 2007, Shanghai, China, May 10-14, 2007.
- 175) Nanomedicine: Evolution, revolution, and transformation, Kazakh National University, Almaty, Republic of Kazakhstan, June 13, 2007.
- 176) Polymers used in controlled drug delivery, Kazakh National University, Almaty, Republic of Kazakhstan, June 14, 2007.

- 177) Polymers in nanotechnology, Kazakh National University, Almaty, Republic of Kazakhstan, June 15, 2007.
- 178) Nanotechnologies in drug delivery, Chungnam National University, Daejeon, South Korea, August 14, 2007.
- 179) Orally disintegrating tablets: Determination of disintegration time, OGD, USFDA, Rockville, MD, August 21, 2007.
- 180) Imaging studies of paclitaxel release from drug-eluting stents. The University of Arizona, Department of Aerospace and Mechanical Engineering, Tucson, AZ, November 8, 2007.
- 181) Hydrotropic polymer micelle for delivery of poorly water-soluble drugs, The 10th European Symposium on Controlled Drug Delivery, Noordwijk aan Zee, The Netherlands, April 2-4, 2008.
- 182) Hydrotropic micelles for poorly water-soluble drugs, Macromolecular Chemistry Symposia, 101th National Meeting of the Korean Chemical Society, Seoul, Korea, April 17, 2008.
- 183) Animal models in drug delivery: Indispensables, limitations and alternatives, The 35th CRS Annual Meeting, New York, NY, July 14, 2008.
- 184) Drug-eluting stents: What need to be done, Kyungpook National University Medical School, Daegu, Korea, September 2, 2008.
- 185) Bioefficacy studies in drug delivery: Animal models and alternatives, The 2008 KCRS Annual Conference: Research Networking for Future Therapy, Jeju Island, Korea, September 4, 2008.
- 186) Macro issues with nano/micro particles for drug delivery, Center for Nanoscale Science and Technology, University of Illinois, Urbana-Champaign, October 1, 2008.
- 187) Hydrotrophic polymer micelles for delivery of poorly soluble drugs, University of Pennsylvania School of Medicine, October 15, 2008.
- 188) Drug delivery systems: Macro issues of nano/micro formulations, University of Wisconsin, School of Pharmacy, Louis W. Busse Lecture Series, November 13, 2008.
- 189) Drug-eluting stents: What now? University of Wisconsin, School of Pharmacy, Louis W. Busse Lecture Series, November 14, 2008.
- 190) Long-term protein delivery: Challenges and opportunities, The 2nd International Quadruple Research Network Symposium - Protein, Gene, Cell Delivery, Hanyang University, Seoul, Korea, December 5, 2008.
- 191) Nanotechnology in drug delivery: Issues & possibilities, Korea Research Institute of Chemical Technology, Taejeon, Korea, December 8, 2008.
- 192) Nano/micro particles with predefined size and shape, 14th International Symposium on Recent Advances in Drug Delivery Systems, Salt Lake City, UT, Feb. 15-18, 2009.
- 193) Delivery of poorly water-soluble drugs: Hydrotropic solubilization and nano/micro-particles, Pfizer, Groton, CT, March 6, 2009.
- 194) Practical nanotechnology and microfabrication for drug delivery, 2009 International Symposium of the Intelligent Drug Delivery System, Seoul, Korea, April 29, 2009.
- 195) Aquatemplate method for microparticulate drug delivery systems, Sungkyunkwan University, College of Engineering, Suwon, Korea, May 1, 2009.
- 196) Polymers in drug delivery systems & gastric retention devices, Astellas Pharma, Shizuoka, Japan, May 22, 2009.
- 197) Drug delivery systems: Basic research and product development, Academy of Pharmaceutical Science and Technology, Japan (APSTJ), Shizuoka, Japan, May 23, 2009.

- 198) Drug-eluting stents: The future trend, the 7th Asia 3 (China-Japan-Korea) Foresight Symposium on Gene Therapy and Biomaterials, Seoul, Korea, May 26, 2009.
- 199) Oral delivery of macromolecular drugs: Limitations and possibilities, 2009 World Class University (WCU) Symposium on Drug Delivery and Bioimaging, Daegu, Korea, May 28, 2009.
- 200) Novel Drug Delivery Systems for Translational Research, Cardiovascular Innovation Seminar Series, Medtronic Cardiovascular, Santa Rosa, CA, August 12, 2009.
- 201) Nanotechnology in drug delivery, Korea Advanced Institute of Science and Technology, Daejeon, Korea, September 1, 2009.
- 202) Nano/micro fabrication for drug delivery systems, Green Cross Pharma, Seoul, Korea, September 2, 2009.
- 203) Nanotechnology in drug delivery, POSTECH, Pohang, Korea, September 3, 2009.
- 204) Macro issue with nano/micro particles in drug delivery, 2009 International Symposium on Crystal Engineering & Drug Delivery System, Tianjin, China, September 6, 2009.
- 205) Advances in drug delivery based on nanotechnology, Ajou University, Suwon, Korea, September 10, 2009.
- 206) Nanotechnology applications for drug delivery, 12th Annual International Conference on Drug Metabolism/Applied Pharmacokinetics, Merrimac, WI, September 17, 2009.
- 207) A new nanofabrication method designed for scale-up production, 7th International Nanomedicine and Drug Delivery Symposium, Indianapolis, IN, October 5-6, 2009.
- 208) Advances in nanofabrication in drug delivery, Advanced Polymeric Materials and Technology Symposium (APMT 2010), Jeju, Korea, January 24-27, 2010.
- 209) The hydrogel template method for nanofabrication of drug delivery particles, The American Society of Mechanical Engineers (ASME)/ the First Global Congress on NanoEngineering for Medicine and Biology (NEMB): Advancing Health Care through Nanoengineering and Computing, Houston, TX, February 8, 2010.
- 210) Nanofabrication of microstructures for drug delivery using the hydrogel template method, Macromolecular Science and Engineering, University of Michigan, Ann Arbor, February 16, 2010.
- 211) Long-term drug delivery using microfabricated particles, Advanced Technologies and Regenerative Medicine (Johnson & Johnson), Somerville, NJ, April 5, 2010.
- 212) A (toy) story of drug delivery systems, Sigma Xi Purdue Chapter, West Lafayette, IN, April 14, 2010.
- 213) Microfabricated particles for controlled drug delivery, Zhejiang University, Department of Chemical and Biochemical Engineering, Hangzhou, China, April 20, 2010.
- 214) Microfabricated particles for controlled drug delivery, Peking University, Department of Polymer Sciences & Engineering, Beijing, China, April 23, 2010.
- 215) Development of large dose FDT formulations & microparticulate depot injectables, CKD Pharmaceutical, Seoul, Korea, April 26, 2010.
- 216) Targeted drug delivery: Essential for further advances in drug delivery, The 9th China-Japan-Korea Foresight Joint Symposium on Gene Delivery and the International Workshop on Biomaterials 2010, Changchun, Jinlin, China, June 21, 2010.
- 217) Drug delivery systems: oral and parenteral formulations, AmorePacific, Suwon, Korea, June 24, 2010.
- 218) Fabrication of long-term release risperidone-PLGA microsystems, Samyang Corp., Daejeon, Korea, June 25, 2010.

- 219) Drug-eluting stents with controllable elution kinetics, SIRIC International Symposium 2010, Stent development: Present and Future, Severance Hospital, Seoul, Korea, July 2, 2010.
- 220) Where have all the smart hydrogels gone? The Annual Controlled Release Society Meeting, Portland, OR, July 14, 2010.
- 221) A new microfabrication method for delivery of various types of drugs, The 19th Shizuoka DDS Conference, Shizuoka, Japan, September 4, 2010.
- 222) Microstructures for drug delivery using the hydrogel template method, University of Tokyo, Tokyo, Japan, September 6, 2010.
- 223) Targeted drug delivery: Expected targeting and true targeting, Tokyo Women's University, Tokyo, Japan, September 7, 2010.
- 224) Wild wild world of drug delivery systems: From macro to nano, Tokyo Institute of Technology, Tokyo, Japan, September 9, 2010.
- 225) Targeted drug delivery: The next advances to be made, The 5th Global COE International Symposium on Frontier in Biomaterials Science and Technology for Regenerative Medicine and Gene/Drug Delivery, Tokyo Institute of Technology, Tokyo, Japan, September 10, 2010.
- 226) Drug targeting: Myth, reality, and possibility, Symposium on Innovative Polymers for Controlled Delivery (SIPCD 2010), Suzhou, China, September 15, 2010.
- 227) Nano-Med: Recent advances in nanotechnology for drug delivery, Suzhou Institute of Nano-Tech and Nano-Bionics, Chinese Academy of Sciences, Suzhou, China, September 16, 2010.
- 228) Long-term protein delivery: Challenges & opportunities, Genentech, South San Francisco, CA, December 2, 2010.
- 229) Recent advances in hydrogel drug delivery for biotherapeutics and major hurdles to commercialization, 46th Annual Pharmaceutical Technologies Arden Conference: Pharmaceutical Development of Biologics: Fundamentals, Challenges, and Recent Advances, The Thayer Hotel, West Point, NY, March 8, 2011.
- 230) Controlled Drug Delivery: Clinically Useful Formulation & Commercial Success, CKD Research Institute, Chonan, Korea, April 27, 2011.
- 231) Drug delivery: New directions in the new decade, The 10th China-Japan-Korea Foresight Joint Symposium on Gene Delivery and International Symposium on Biomaterials 2011, Gulin, Guangxi, China, May 31, 2011.
- 232) Controlled drug delivery technologies for clinically useful practical formulations, Changchun Institute of Applied Chemistry, Changchun, China, June 3, 2011.
- 233) Barriers to overcome for targeted drug delivery to tumors, Drug Delivery and Cancer: Challenges and New Directions for Cancer Therapy, West Lafayette, IN October 10, 2011.
- 234) The 10Xer's way toward theragnosis, Korea Institute of Science and Technology, Seoul, Korea, November 24, 2011.
- 235) How smart is a smart hydrogel? Yeongnam University, Daegu, Korea, November 25, 2011.
- 236) Infinite future of undergraduate students, Korea University, School of Pharmacy, Jochiwon, Korea, November 28, 2011.
- 237) Targeted drug delivery: myth, reality, & possibility, Department of Pharmaceutical Sciences, University of Tennessee Health Science Center, Memphis, TN, December 12, 2011.
- 238) Controlled drug delivery: The third generation, International Symposium on Past, Present and Future of Molecular Pharmacokinetics, Hitotsubashi Hall, Tokyo, Japan, January 18, 2012.

- 239) Targeted drug delivery: myth, reality, & possibility, Department of Mechanical Engineering, University of Minnesota, Minneapolis, MN, March 28, 2012.
- 240) Nanoadvances in nanotechnology-based drug delivery, KAIST, Daejeon, Korea, April 16, 2012.
- 241) Drug delivery systems for the new decades: Balance between “*iNew*” and “Me-too” approaches. National Tsing Hua University, Hsinchu, Taiwan, April 26, 2012.
- 242) Publication of papers for Journal of Controlled Release. Changchun Institute of Applied Chemistry, Chinese Academy of Sciences, Changchun, China, June 1, 2012.
- 243) How to write good papers for JCR. West China School of Pharmacy, Sichuan University, Chengdu, China, June 2, 2012.
- 244) The 3rd Generation drug delivery systems: Issues to Resolve. The 9th World Biomaterials Congress, Chengdu, China, June 3, 2012.
- 245) Politicians, Athletes, Scientists, and *iCRS*. The 39th Annual Meeting of the Controlled Release Society, Quebec, Canada, July 17, 2012.
- 246) Drug Delivery Systems for the New Decade: Balance between “*iNew*” and “Me-too” Approaches, the 15th International Biotechnology Symposium, Daegu, Korea, September 17, 2012.
- 247) The 3rd Generation drug delivery systems: Back to Basics, the 3rd Asymchem Pharmaceutical CMC 2012, Tianjin, China, September 21, 2012.
- 248) The 10X Research on Drug Delivery, Sungkyunkwan University, Korea, September 24, 2012.
- 249) The 3rd generation drug delivery systems: Improvement to make, Peking University, Beijing, China, December 1, 2012.
- 250) Controlled Drug Delivery Systems, CoSci-Med, Harbin, China, December 2, 2012.
- 251) Controlled drug delivery systems for the new decade, Heilongjiang University, Harbin, China, December 3, 2012.
- 252) Oral controlled drug delivery systems, Symposium on New Technology Seminar on Extended and Controlled Release Oral Solid Dosage (VIII), Guangzhou, China, December 4, 2012.
- 253) Controlled release formulations for generics, The 3rd International Forum for Generics, Nanchang, China, December 5-6, 2012.
- 254) Anti-retroviral delivery systems: New directions in the new decades, NIH National Institute of Allergy and Infectious Diseases, Division of AIDS, Prevention Sciences Program and The Bill and Melinda Gates Foundation. Think Tank on Drug Delivery Systems for HIV Prevention, Washington, DC, February 22, 2013.
- 255) Controlled drug delivery systems: The third generation, International Conference on Biomaterials Science, Tsukuba, Japan, March 20-22, 2013.
- 256) Targeted drug delivery: Insights by Professor You Han Bae, Joint Symposium of the 5th Utah-Inha DDS Research Center Symposium and the 7th International Symposium on Intelligent DDS, Incheon, Korea, May 23-24, 2013.
- 257) The missing components of current drug delivery systems and new approaches, The 4th International Advanced Biomaterials Symposium Changchun, China, September 28-30, 2013.
- 258) Facing the truth about nanotechnology in drug delivery, Dongguk University, Pharmacy School in Ilsan. October 2, 2013.
- 259) Controlled drug delivery: new technologies required for the next generation, Symposium on Perspectives on the Future of Drug Delivery Systems, Beijing, China, November 22, 2013.

- 260) Controlled drug delivery: Challenges and Opportunities, Youbo Pharmaceuticals, Mudanjiang, China. March 10, 2014.
- 261) The 3rd generation drug delivery systems: Future back, the 8th International Symposium on Intelligent Drug Delivery System, Seoul, Korea, April 24, 2014.
- 262) Create your own future, Korea University, Jochiwon, Korea, May 28, 2014.
- 263) Controlled drug delivery: Historical perspective for the future, Ajou University, Suwon, Korea. November 3, 2014.
- 264) Virtual human, KIST, Seoul, Korea, November 4, 2014.
- 265) From pills to nanoparticles: The 10X progress in drug delivery research, Korean-American Society in Biotech and Pharmaceuticals (KASBP), Morristown, NJ, November 7, 2014.
- 266) 30 Years of Research on Drug Delivery: A Personal Reflection, Purdue University Faculty Careers Colloquium, West Lafayette, IN, February 20, 2015.
- 267) Vacuum SpinSwiper for microfabrication of PLGA microparticles, Sungkyunkwan University, Suwon, Korea, March 24, 2015.
- 268) Controlled drug delivery: Historical perspective for the next generation, Pharmaceutical Society Japan, Kobe, Japan, March 28, 2015.
- 269) Drug delivery technologies for the future: Thinking in new boxes, Ashland Inc. Distinguished Lecturer at the University of Kentucky, April 27 2015.
- 270) Controlled drug delivery systems: Needs for accelerated evolution, the Canadian Biomaterials Society, Toronto, Canada, May 29, 2015.
- 271) Drug delivery of the future: Chasing the invisible gorilla, The 1st Annual International Symposium on Bio-Therapeutics Delivery, Seoul, Korea, September 14, 2015.
- 272) Sustained depot formulations for parenteral applications, CJ HealthCare, Icheon-si, Gyeonggi-do, Korea, September 18, 2015.
- 273) PLGA microparticle formulations for long-term drug delivery, Korea University, Jochiwon, Korea, September 21, 2015.
- 274) Drug delivery of the future: Chasing the invisible gorilla, Lilly/Purdue Technology Day, Eli Lilly, Indianapolis, IN, October 5, 2015.
- 275) Controlled Drug Delivery: Historical perspective for the next generation, Sungkyunkwan University, College of Engineering and College of Pharmacy, Suwon, Korea, November 19, 2015.
- 276) Controlled Drug Delivery: Historical perspective for the future, The Chinese University of Hong Kong, College of Pharmacy, Sha Tin, Hong Kong, March 16, 2016.
- 277) Lessons learned from Dr. Tsuneji Nagai for the future of drug delivery, the 30th Anniversary Symposium of The Nagai Foundation Tokyo: Link to the Past and Bridge to the Future, Tokyo, Japan, July 7, 2016.
- 278) Drug Delivery Systems: Achieving Accelerated Evolution, the 10th Israel Controlled Release Society Symposium, Maalot, Israel, September 16, 2016.
- 279) Drug Delivery Systems: Accelerated Evolution for the Future, Allan S. Hoffman Lecture, University of Washington, Seattle, WA, October 10, 2016.
- 280) Drug delivery systems: Past successes and future possibilities, the 28th Korean Academy of Science & Technology Symposium: Young Scientists in Drug Delivery- Redirecting the Research Field, KIST, Seoul, Korea, December 7, 2016.

- 281) PLGA microparticles; Challenges in peptide and protein delivery, Eli Lilly and Company, Indianapolis, IN, March 9, 2017.
- 282) Center for drug abuse intervention and treatment, National Institute of Drug Abuse, Baltimore, MD, April 7, 2017.
- 283) The drug delivery field at the inflection point, IDDS-GiRC Joint Symposium, Seoul, Korea, May 25, 2017.
- 284) The drug delivery field at the inflection point: Why we need to change, University of Utah, Salt Lake City, UT, August 28, 2017.
- 285) Characterizations of PLGA polymers, FDA Public Workshop on Demonstrating Equivalence of Generic Complex Drug Substances and Formulations: Advances in Characterization and In Vitro Testing, Silver Spring, MD, October 6, 2017.
- 286) The drug delivery field at the tipping point, Korea University, Jochiwon, Korea, October 20, 2017.
- 287) Drug delivery systems: Accelerated evolution for the future, Monash University, Melbourne, Australia, November 17, 2017.
- 288) Preparing manuscripts and patents, University of Auckland, Auckland, New Zealand, November 21, 2017.
- 289) Bioefficacy and toxicity studies in drug delivery: Animal models & alternatives, in New Zealand-Australia CRS 2017 Joint Workshop on Recent Trends in In-vitro, Ex-vivo and In-vivo Models in Bioactive Delivery, November 22, 2017.
- 290) Drug delivery systems: Past successes and future possibilities, University of Otago, Dunedin, New Zealand, November 24, 2017.
- 291) Preparing manuscripts for Journal of Controlled Release, University of Otago, Dunedin, New Zealand, November 24, 2017.
- 292) The drug delivery field at the inflection point: Time for new thinking, University of Auckland, Auckland, New Zealand, November 27, 2017.
- 293) Role of drug delivery in drug discovery, University of Auckland, Auckland, New Zealand, November 28, 2017.
- 294) The drug delivery field at the inflection point: Time to change for the future, University of Southern California, Los Angeles, CA, February 24, 2018.
- 295) The drug delivery field at the inflection point, The KAST 13th Frontier Scientist Workshop: Future Trends of Biomaterials, University of Utah, Salt Lake City, UT, June 18-19, 2018.
- 296) A long walk to PLGA. The 2018 Annual Meeting of Controlled Release Society, New York, NY, July 22, 2018.
- 297) The future of the drug delivery field: Lessons learned from Professor Diane Burgess, The Interface between Science and Education. A Celebration of Professor Diane J. Burgess' 60th Birthday, Storrs, CT, August 18, 2018.
- 298) PLGA microparticles: Very well-known but unexplored formulations, Fifth Symposium of Innovative Polymers for Controlled Delivery, Suzhou, China, September 15, 2018.
- 299) The drug delivery field at the inflection point: Time to think differently, West China School of Pharmacy, Sichuan University, Chengdu, China, November 5, 2018.
- 300) The drug delivery field at the inflection point: Time to think differently, Engineering Research Center in Biomaterials, Sichuan University, Chengdu, China, November 6, 2018. West China School of Pharmacy, Sichuan University, Chengdu, China, November 6, 2018.

- 301) Create your own future, West China School of Pharmacy, Sichuan University, Chengdu, China, November 6, 2018.
- 302) One life, one chance, Purdue Korean Faculty Association, West Lafayette, IN, December 14, 2018.
- 303) The future of the drug delivery field: time to make real changes, 17th International Symposium on Advances in Technology and Business Potential of New Drug Delivery Systems, Mumbai, India, February 2, 2019.
- 304) Characterization considerations for complex generics containing PLGA, Section "Advancing Pharmaceutical Science in Generic Industry-1), 33rd International Forum Processing Analysis & Control (IFPAC-2019), North Bethesda, MD, March 4, 2019.
- 305) Drug delivery: Collective progress beyond nanohorizon, Nanomedicine Symposium, Aurora, CO, April 26, 2019.
- 306) An assessment of the current and likely impact of the science of crossing biological barriers on medicine, Keystone Symposium on Delivering Therapeutics across Biological Barriers, Dublin, Ireland, May 9, 2019.
- 307) PLGA: Very well-known but unknown polymers, Helmholtz-Zentrum Geesthacht. Centre for Materials and Coastal Research, Berlin, Germany, May 14, 2019.
- 308) Nanoprogess in nanomedicine: Mission NanoAccomplished, 2019 Controlled Release Society (CRS) Annual Meeting, Debate on Nanotechnology: Big progress vs nano progress, Velencia, Spain, July 22, 2019.
- 309) Importance of polymer characterization in transdermal and cosmetic formulations, Fifth Conference of transdermal drug delivery in world federation of Chinese medicine societies, Nanjing. China, August 17, 2019.
- 310) One life, one chance: Create your own future, China Pharmaceutical University, Nanjing, China, August 19, 2019.
- 311) PLGA formulations: Understanding the complexicity of the PLGA assay, Chinese American Society of Nanomedicine and Nanotechnology, Hangzhou, China, August 20, 2019.
- 312) Kinam Park and Fernanda Ogochi: How to get published in Journal of Controlled Release: Perspectives of the editor and the publisher, Chinese American Society of Nanomedicine and Nanotechnology, Hangzhou, China, August 20, 2019.
- 313) Characterization of complex PLGA formulations, FDA, Silverspring, MD, September 12, 2019.
- 314) Kinam Park and Fernanda Ogochi: Writing research articles, West China School of Pharmacy, Chengdu, China, September 19, 2019.
- 315) Reshapable hydrogels for soft tissue expansion, Engineering Research Center in Biomaterials, Sichuan University, Chengdu, China, September 19, 2019.
- 316) Drug Delivery: What Do We Do Now? The 1st Asian Young Investigator Symposium on Pharmaceutical Science and Technology, Chengdu, China, September 20, 2019.
- 317) Professor Doo Sung Lee: A pioneer in environment-sensitive polymers, Polymer Society of Korea, Seogwipo, Jeju, Korea, October 10, 2019.
- 318) Stand firm on the goal of your life, College of Pharmacy, Seoul National University, Seoul, Korea, October 11, 2019.
- 319) Time for Korean pharmaceutical science to move ahead of the world, Pharmaceutical Society of Korea, Yeosu, Korea, October 14, 2019.

Awards by Graduate students

- 1) Yoon Yeo: 2002 CRS-3M Drug Delivery Systems Graduate Student Outstanding Research Award in Drug Delivery (Controlled Release Society, July, 2003)
- 2) Yong Qiu: AAPS Outstanding Graduate Student Research Award in Pharmaceutical Technologies (American Association of Pharmaceutical Scientists, October 2003)
- 3) Yoon Yeo: AAPS Outstanding Graduate Student Research Award in Pharmaceutical Technologies (American Association of Pharmaceutical Scientists, November 2004)
- 4) Drug Delivery Special Interest Group Outstanding Contribution to the Society for Biomaterials (Eunah Kang: Society for Biomaterials 2007)

Reviewer for Scientific Organizations

- 1) Reviewer for the Petroleum Research Fund of the American Chemical Society (1991, 1992, 1994, 1997, 2000).
- 2) Special reviewer for the Medical Research Council of Canada (1991, 1996), and the National Sciences and Engineering Research Council of Canada (1998, 2001).
- 3) Reviewer for the U.S. Civilian Research & Development Foundation. Regional Experimental Support Center Program 2000-2001 (2000).
- 4) Reviewer for the Maryland Sea Grant College of the National Office's Sea Grant Technology Program (2002)
- 5) Reviewer for Canadian Institute of Health Research (2003)
- 6) Reviewer for Connecticut Innovations (2005)
- 7) Reviewer for the Netherlands Organisation for Scientific Research (2009)
- 8) Reviewer for the BMM/CTMM/TIPharma, the Netherlands (2009)
- 9) Reviewer for Lister Institute Research Prizes, United Kingdom (2012)

Reviewer for Academic Departments

- 1) University of Minnesota, Department of Pharmaceutics, 1998
- 2) University of Utah, Department Pharmaceutics and Pharmaceutical Chemistry, 2004.
- 3) School of Pharmacy at Queen's University Belfast, Belfast, United Kingdom, 2011.

Short Course Instructor

- 1) Peppas, N.A. and Park, K.: Hydrogels in Biomedical and Pharmaceutical Applications, held at Indianapolis, IN, on April 24-26, 1991.
- 2) Peppas, N.A. and Park, K.: Hydrogels in Biomedical and Pharmaceutical Applications, held at Purdue University, West Lafayette, IN, on May 5-7, 1992.

National and International Committee Member

- 1) Program Planning Committee for the American Association of Pharmaceutical Scientists (AAPS) Meeting (Fall, 1987).
- 2) Scientific Program Committee for the 1990 Controlled Release Society Meeting (July, 1990).

- 3) Abstract review for the Pharmaceutics and Drug Delivery Section of the American Association of Pharmaceutical Scientists (AAPS) Meeting (Fall, 1991).
- 4) Program Planning Committee for the Controlled Release Society Symposium to be held in Korea (1992).
- 5) Controlled Release Society Award Committee in Outstanding Pharm/Ag-Vet Section (1992-1993).
- 6) Controlled Release Society Award Committee in Graduate Student Research Awards & Young Investigator Research Award (1993-1996)
- 7) Controlled Release Society Nominations Committee (1993-1996).
- 8) Controlled Release Society Committee in Ag/Vet Development (1993-1996).
- 9) Abstract review for the Protein Adsorption Section of the Society for Biomaterials Meeting (1993).
- 10) Task Force on Global Membership Network of the Controlled Release Society (1993).
- 11) Controlled Release Society Award Committee in Outstanding Pharm/Ag-Vet Section (1993-1994).
- 12) Abstract review committee for the 20th Annual Meeting of the Society for Biomaterials (held in Boston, April 5-9, 1994).
- 13) Advisory Board of the Molecular Modeling Conference (1994)
- 14) Scientific Program Committee for the 1996 Controlled Release Society Meeting (1994).
- 15) Chairman of the Global Network Team of the Controlled Release Society (1994-1995).
- 16) Advisory Panel on Polymeric Excipients, USP (1995-1999)
- 17) Chairman of the Global Network Committee of the Controlled Release Society (1995-1996).
- 18) Chairman of the Fellow selection committee of the Pharmaceutics and Drug Delivery (PDD) section of the American Association of Pharmaceutical Scientists (AAPS) (1996-1997).
- 19) ACS Books Advisory Board (1997-2000)
- 20) Advisory Panel on Current Drugs (1997-1999)
- 21) Scientific Advisory Board, International Symposium on the Frontiers in Biomedical Polymers Applications (2000-2001)
- 22) Scientific Advisory Board, International Symposium on Recent Advances in Drug Delivery Systems (2000-2001)
- 23) Advisory Panel on Excipients: Substance and Characterization Expert Committee, USP (2000-2005)
- 24) Scientific Program Committee of the 2nd Pharmaceutical Sciences World Congress (PSWC2004) (2001-2004).
- 25) Workshop Committee for the Controlled Release Society's Workshop on Optimization of Quality and Performance Attributes of Controlled Release Products, Seoul, Korea (2001-2002)
- 26) International Advisory Committee of the First International Conference on Medical Implants Bethesda, MD (July 25-28, 2003)
- 27) Scientific Advisory Board, Third International Nanomedicine and Drug Delivery Symposium (2005)
- 28) Scientific Advisory Board, European Symposium on Controlled Drug Delivery (2006-)
- 29) Scientific Advisory Board, China International Pharmaceutical Technologies Conference 2007 (2006-)
- 30) Scientific Organizing Committee for Micro 2007, The 16th International Symposium on Microencapsulation (2007)

- 31) International Advisory Board, the 3rd International Conference on Smart Materials, Structures and Systems (2007-2008)
- 32) International Organizing Committee, Symposium on Innovative Polymers for Controlled Delivery, Suzhou, China, September 14-17, 2010.
- 33) Nominations Committee for Controlled Release Society, 2010-2011.
- 34) Symposium Co-Chairman, 4th International Advanced Biomaterials Symposium 2013, September 28-October 2, 2013, Changchun, China.
- 35) International Committee of the Athens Congress on Computational-Experimental, Scientific-Regulatory Advances in Drug Discovery, Formulation Strategies, Drug Delivery, ADMET for Small Molecules (Generics) and Biotechnological (Biosimilar) Drugs, Athens, Greece, May 30-June 1, 2015.
- 36) The Annual Meeting Programme Committee for the Controlled Release Society conference in 2015, Edinburgh, Scotland, July 25-29, 2015.
- 37) The nominating committee of the Controlled Release Society, 2016-2017.
- 38) The nominating committee of the Controlled Release Society, 2017-2018.

Meeting Organizer

- 1) The 1989 Scanning Microscopy Meeting on "Colloidal gold: quantitative labeling and new applications," held in Salt Lake City, UT, on May 1-5, 1989.
Co-organizer: Dr. Ralph Albrecht, University of Wisconsin.
- 2) The 1994 ACS National Meeting on "First International Symposium on Biorelated Polymers," sponsored by the Division of Polymer Chemistry, held in Washington, D.C., on August 21-25, 1994.
Co-organizers: Dr. Raphael Ottenbrite, Virginia Commonwealth University, and Dr. Samuel Huang, University of Connecticut.
- 3) Organizer for the workshops on "Particulate Drug Delivery Systems" and "Development of Hydrogel dosage forms" of the 1996 Controlled Release Society Meeting in Kyoto, Japan on July 11-12, 1996.
- 4) A member of the organizing committee for the First Asian International Symposium on Polymeric Biomaterials Science, held in Ishikawa, Japan on May 14-16, 1997.
- 5) KSP and CRS Joint Symposium on Recent Advances in Drug Delivery and Biomaterials, held in Seoul, Korea on September 24-26, 1997.
Program co-chairman: Seo Young Jeong
- 6) The 1998 Controlled Release Society Meeting, held in Las Vegas on June 22-24, 1998.
Program co-chairman: Russell Potts.
- 7) Program Chairman for "Recent Advances in Controlled Drug Delivery," in The WorldPharm98, held in Philadelphia, PA on September 22-24, 1998.
- 8) American Chemical Society Symposium on "Drug Delivery in the 21st Century" sponsored by the Division of Polymer Chemistry, held in Anaheim, CA on March 21-25, 1999.
Co-organizer: Randall Mersny.
- 9) The Controlled Release Society Winter Symposia and 11th International Symposium & Exposition on Recent Advances in Drug Delivery Systems, held in Salt Lake City, UT on March 3-6, 2003.
Co-organizers: Jindrich Kopecek, James Anderson, Martyn Davies, Sung Wan Kim.

10) The workshops on "CMC Regulatory Issues for Controlled Release Parenterals," of the 2006 Controlled Release Society Meeting in Vienna, Austria on July 22, 2006. Co-organizer: Diane Burgess.

11) International Symposium on Recent Advances in Drug Delivery, held in Salt Lake City, UT on February 26-28, 2007.

Co-Chairmen: David Granger and You Han Bae.

12) Program Chairman of the Annual Meeting of the Society for Biomaterials held in Chicago, IL, 2007.

13) Program Chair for the pharma themes (Chemistry for Health: Catalyzing Translational Research) for the ACS Annual Meeting, held in Philadelphia, PA, in August 2008.

14) International Symposium on Recent Advances in Drug Delivery, held in Salt Lake City, UT on February 15-17, 2009.

Co-Chairmen: David Granger and You Han Bae.

15) Drug Delivery and Cancer: Challenges and New Directions for Cancer Therapy, held in West Lafayette, IN on October 10-11, 2011,

Co-Chairmen: Alex Wei, Donald Berstrom, and Kinam Park.

16) Chair, the Annual Meeting Programme Committee for the Controlled Release Society conference in 2016, Seattle, WA, USA, July 16-20, 2016.

17) Co-Chair, Randy Mrsny, Kinam Park, Isabelle Aubert, and Cornell Stamoran, Chairs. Non-invasive Delivery of Macromolecules Conference 2017, San Diego, CA, USA, February 21-24, 2017.

Chairman at Meetings

1) Chairman of a section on "Artificial Surfaces" at the 1986 Scanning Electron Microscopy Meeting, held in New Orleans, LA, on May 5-9, 1986.

2) Chairman of a section on "Bioadhesives" at the 14th International Symposium on Controlled Release of Bioactive Materials, held in Toronto, Canada, on August 2-5, 1987.

3) Chairman of a session on "Ancillary and Correlative Techniques II - Labeling," at The 7th Pfefferkorn Conference on Science of Biological Specimen Preparation, held in Guildford, England, on September 12-16, 1988.

4) Chairman of a section on "Biopharm I" at the 17th International Symposium on Controlled Release of Bioactive Materials, held in Reno, NV, on July 22-25, 1990.

5) Chairman of a session on "Vascular Prosthesis" at the 38th Annual Meeting of American Society for Artificial Internal Organs, held in Nashville, TN, on May 7-9, 1992.

6) Chairman of a session on "Fourth International Symposium on Polymeric Drugs and Drug Delivery Systems" at the 204th ACS National Meeting, held in Washington, D.C., on August 24, 1992.

7) Co-Chairman of a session on "Polymers of Biological and Biomedical Significance" at the 204th ACS National Meeting, held in Washington, D.C., on August 26, 1992.

8) Co-Chairman of a session on "Bioadhesives" at the AIChE Annual Meeting, held in Miami Beach, FL, on November 4, 1992.

9) Co-Chairman of a session on "Mathematical and Computer Modeling" at the 22nd International Symposium on Controlled Release of Bioactive Materials, held in Seattle, WA, on July 30-August 2, 1995.

- 10) Co-Chairman of a session on "Biomaterials and Drug Delivery" at the 42nd Annual Conference of American Society for Artificial Internal Organs, held in Washington, D.C., on May 3, 1996.
- 11) Chairman of a session on "Transdermal Products Development" at the Third International Symposium on Biomaterials and Drug Delivery Systems, held in Taejeon, Korea, on July 4-5, 1996.
- 12) Co-Chairman of a section on "Agriculture/Veterinary Applications 1 - Session II" at the 23rd International Symposium on Controlled Release of Bioactive Materials, held in Kyoto, Japan, on July 7-10, 1996.
- 13) Chairman of a session on "Biorelated Polymers: Advances in Polymeric Drugs and Drug Design" at the 212th American Chemical Society National Meeting, held in Orlando, FL, on August 25-29, 1996.
- 14) Chairman of a session on "Polymer Design I" at the 8th International Symposium on Recent Advances in Drug Delivery Systems, held in Salt Lake City, UT, on February 24-27, 1997.
- 15) Chairman of 7 sessions of "Recent Advances in Controlled Drug Delivery" at The WorldPharm98, held in Philadelphia, PA, on September 22-24, 1998.
- 16) Chairman of a session on "Polymeric Carriers" at the 8th International Symposium on Recent Advances in Drug Delivery Systems, held in Salt Lake City, UT, on February 19-22, 2001.
- 17) Chairman of a session on "Issues in Protein Microencapsulation" at the AAPS Conference on Advances in Pharmaceutical Processing, held in Parsippany, NJ, on June 19-20, 2003.
- 18) Co-Chairman of a session on "Colloidal Drug Carriers" at the 32nd Annual Meeting of the Controlled Release Society, held in Miami, FL, on June 18-22, 2005.
- 19) Co-Chairman of a session on "Industrial Session and Roundtable: From Bench to Bedside" at the NanoDDS 10, held in Omaha, NE, on Oct. 3-5, 2010.
- 20) Co-Chairman of a session on "New Concepts in Polymer Gene/drug/RNAi Delivery Systems" (SO51-16.2) at the 9th World Biomaterials Congress, held in Chengdu, China on June 3, 2012.
- 21) Co-Chairman of a session on "Preparation and Biomedical Applications of Bioactive Polymer Materials" (SO52-33 & SO64-33) at the 9th World Biomaterials Congress, held in Chengdu, China on June 3, 2012.
- 22) Chairman of a Plenary Session by Dr. Kenzo Takada at the Controlled Release Society Meeting in Honolulu, Hawaii, July 22, 2013.
- 23) Co-Chairman of a session on Parenteral Sustained Release Drug Delivery at the Controlled Release Society Meeting in Honolulu, Hawaii, July 22, 2013.
- 24) Chairman of a session on Blood-Brain Barrier at the Non-invasive Delivery of Macromolecules Conference 2017, San Diego, CA, USA, February 22, 2017.
- 25) Co-chairman of Session 4, Fifth Symposium of Innovative Polymers for Controlled Delivery, Suzhou, China, September 16, 2018.

Teaching Responsibility

- 1) IPPH 363: Basic Pharmaceutics II: Controlled release drug delivery systems (1986-2006, 2009)
- 2) IPPH 581: Disperse Systems: physicochemical and thermodynamic properties of polymers used in the pharmaceutical area. (1986-1996)
- 3) IPPH 669: Rate Processes: Rate processes occurring in biological systems. (1987-1995)
- 4) BMS 517A: Tissue engineering (on biomaterials and drug delivery) (2000)
- 5) ChE 697C: Biomaterials Science (on biomaterials and drug delivery) (2001)

- 6) IPPH 690W: (BME695K): Polymers in Pharmaceutical and Biomedical Systems (2000 - 2014)
- 7) ChE 461: Biomedical Engineering (2008 - 2018)
- 8) Engr 103: Introduction to Engineering Practice (2008 - 2018)
- 9) BME 290: Frontiers in Biomedical Engineering (2010)
- 10) IPPH 100: Orientation Course (2017 - 2018)
- 11) BME 295/299: BME Research Scholars I (2017)
- 12) BME 489/490: BME Senior Design (2018)
- 13) BME 695K: Polymers in Biomedical and Pharmaceutical Systems (2016 -)

Thesis Supervision

- 1) Donghao Robert Lu - "Protein behavior at the solid-liquid interface."
He graduated with a Ph.D. degree in August 1990 to become Assistant Professor at Idaho University.
- 2) Fei-Wen Mao - "Polymer grafting and steric repulsion."
She graduated with a M.S. degree in April, 1990.
- 3) Waleed S.W. Shalaby - "Enzyme-digestible hydrogels for oral drug delivery"
He graduated with a Ph.D. degree in July 1992. He continued his education at the School of Medicine of the University of South Carolina and obtained his M.D. degree in 1996.
- 4) Mansoor M. Amiji - "Steric repulsion by PEO/PPO/PEO block copolymers"
He graduated with a Ph.D. degree in August 1992 to become Assistant Professor at School of Pharmacy, Northeastern University.
- 5) Kalpana R. Kamath - "Albumin grafting by γ -irradiation"
She graduated with a Ph.D. degree in August 1993 to become Assistant Professor at School of Pharmacy, University of South Dakota.
- 6) Samuel J. Lee - "Synthesis of sol-gel phase-reversible hydrogels sensitive to glucose"
He graduated with a Ph.D. degree in December 1994 to work as a research scientist at DuPont Biomedical.
- 7) Timothy B. McPherson - "Prevention of protein adsorption by PEO surface modification"
He graduated with a Ph.D. degree in December 1995. After working as a postdoc in Bioengineering Department of Purdue University, he became Assistant Professor at College of Pharmacy, Saint Louis University.
- 8) Aiman A. Obaidat - "Characterization of glucose dependent gel-sol phase transition of the polymeric glucose-concanavalin a hydrogel"
He graduated with a Ph.D. degree in June 1996 to become Assistant Professor at School of Pharmacy, Jordan University of Science and Technology, Irbid, Jordan.
- 9) Jun Chen - "Superporous hydrogels: Synthesis and applications"
He graduated with a Ph.D. degree in January 1997 to work as a research scientist at Merck.
- 10) Rosalind Jackson - "Preparation of alginate microparticles by emulsification for oral vaccine delivery"
She graduated with a Ph.D. degree in May 1997 to work as a research scientist at McNeil Consumer Products Company.

- 11) Seongbong Jo - "Synthesis of applications of silanated poly(ethylene glycol)s"
He graduated with a Ph.D. degree in May 1998.
- 12) Argaw Kidane - "PEO grafting on biomaterial surfaces using gamma-irradiation"
He graduated with a Ph.D. degree in May 1996 to work at Upjohn Company.
- 13) Tonglei Li - "Fractal analysis of surface roughness and study of etching mechanism of acetaminophen single crystals"
He graduated with a Ph.D. degree in April 1999 and became an Assistant Professor at University of Kentucky.
- 14) Richard Gemeinhart - "Properties of superporous hydrogels for drug delivery"
He graduated with a Ph.D. degree in 2000 and became an Assistant Professor at University of Illinois at Chicago.
- 15) Jung Ju Kim - "Glucose-sensitive phase-reversible hydrogels"
He graduated with a Ph.D. degree in 2001 and became a group leader at Pacific Corporation in Korea.
- 16) Nam-Jin Baek - "Drug delivery from stents"
Graduated with a Ph.D. degree in July 2002 and became a group leader at Samyang Research Center-USA.
- 17) Hong Wen-"Atomic force microscopic examination of crystal dissolution patterns."
Graduated with a Ph.D. degree in September 2002. Wyeth Pharmaceutical Inc.
- 18) Yong Qiu - "Development of elastic superporous hydrogels."
Graduated with a Ph.D. degree in December 2002 and is now with IMPAX Laboratories, Inc.
- 19) Yoon Yeo-"Solvent exchange method- a novel microencapsulation technique."
Graduated with a Ph.D. degree in November 2003 and is now on the faculty at Purdue University.
- 20) Mark E. Byrne (NSF IGERT Fellow, Department of Chemical Engineering) - "Glucose sensitive molecules: Applications to biosensors" (Co-advisor with Professor Nicholas Peppas at Department of Chemical Engineering).
Graduated with a Ph.D. degree in 2003 and is now an Assistant Professor at Auburn University.
- 21) Yourong Fu - "Novel method of making fast dissolving tablets"
Graduated with a Ph.D. degree in 2004 and is now with Akina, Inc.
- 22) David Henthorn (NSF IGERT Fellow, Department of Chemical Engineering) - "Modeling of novel multi-methacrylate polymerization" (Co-advisor with Professor Nicholas Peppas at Department of Chemical Engineering).
Graduated with a Ph.D. degree in 2004. Assistant Professor at University of Missouri-Rolla.
- 23) Kimberly Hayden (NSF IGERT Fellow, Department of Chemical Engineering) - "Effect of particle surface characteristics on particle transport" (Co-advisor with Professor Jennifer Sinclair at Department of Chemical Engineering).
Graduated with a Ph.D. degree in 2003 and is now an Assistant Professor at University of Missouri-Rolla.

- 24) Jay Blachard (NSF IGERT Fellow, Department of Biomedical Engineering) - "Controlled drug delivery using pH-sensitive hydrogels" (Co-advisor with Professor Nicholas Peppas at Department of Chemical Engineering).
August 2000 - December 2002 (Moved to University of Texas at Austin).

- 25) Grace Jun-Park (NSF IGERT Fellow, Department of Pharmaceutics) - "Surface modified PLGA/carbon nanofiber composites enhance articular chondrocyte functions" (Co-advisor with Professor Tom Webster at Department of Biomedical Engineering).
Graduated with a Ph.D. degree in December 2005 and is with Becton, Dickinson & Co. (BD) at Franklin Lakes, NJ.

- 26) Seonghoon Jeong- "Sustained release of fast-melting tablets using various polymer coated ion-exchange resin complexes"
Graduated with a Ph.D. degree in 2005. Wyeth Pharmaceuticals
Professor at Busan National University in Korea.

- 27) Connie Paul (NSF IGERT Fellow, Department of Pharmaceutics)- "The microenvironment-controlled encapsulation (mice) process for drug delivery" Co-advisor with Professor Paul Robinson at School of Veterinary Sciences).
Graduated with a Ph.D. degree in August 2006 and is currently an associate scientist with Elan Pharmaceuticals.

- 28) Eunah Kang-"Drug eluting stent and its characterization by coherent anti-Stokes Raman scattering microscopy"
Graduated with a Ph.D. degree in Biomedical Engineering in 2007
A postdoc at Korea Institute of Science and Technology.

- 29) Mingli Ye- "Factors controlling the microcapsules prepared by the solvent exchange method"
Graduated with a Ph.D. degree in 2008.
A postdoctoral research associate with the Engineering Research Center for Structure Organic Particulate Systems, School of Chemical Engineering, Purdue University.

- 30) Kwang Su Seo - "Novel ultrasonic atomizer approach for making microcapsules"
Graduated with a master's degree in Biomedical Engineering in 2006.
A Ph.D. graduate student at University of Akron.

- 31) Kumar Vedantham - "Development of two-drug eluting stents"
August 2005 - October 2009
Postdoc training at Mechanical Engineering and Engineering Science Department, The University of North Carolina at Charlotte.

- 32) Somali Chaterji - "Endothelial cell culture on smooth muscle cell surface"
August 2005 - December 2009.

- 33) Ji Young Kim - "Hydrotropic solubilization of poorly soluble drugs"
January 2006 -August 2009
LG Life Science.

- 34) Jutarat Kitsongsermthorn - "Multiple drug release from stents"
August 2006 –October 2011.

- 35) Namho Kim - "Drug release for promoting endothelial cell growth"

August 2008 - July 2010.

- 35) Ying Lu- "Drug-eluting stents using nanofabricated drug crystals"
July 2009 - 2013.
- 36) Yuanzu He- "Effect of microparticle shape and size on cell endocytosis"
July 2010 - 2012.
- 37) Crystal Soo Jung Shin: "Nanofabrication of anticancer drug delivery systems"
January 2010 - June 2014.
- 38) Matthew McDermot: "An evaluation of tetramethyl orthosilicate as a vehicle for anti-inflammatory delivery after microelectrode implantation"
July 2011 - present (Co-advisor: Professor Kevin Otto).
- 39) Mark Hamilton- "Blood glucose detection from exhaled breath condensate"
May 2012 - May 2014 (Co-advisor: Professor Ann Rundell).
- 40) Ben Kline - "Interplay between polymer and solvent in microparticle formulation"
July 2012 - May 2014.
- 41) Heui Chang Lee- "Device design factors for enhancing the functionality of chronic intracortical microelectrodes"
July 2012 - December 2016 (Co-advisor: Professor Kevin Otto).

Post-docs and visiting scientists

- 1) Professor Chang-Koo Shim, Ph.D., November, 1988 - October, 1989.
- 2) Yin-Chao Tseng, Ph.D., July, 1989 - June, 1992.
- 3) Annamaria Paparella, Ph.D., October, 1993 - May, 1994.
- 4) Professor Sung-Ju Hwang, Ph.D., June, 1996 - June, 1998.
- 5) Jin-Chul Kim, Ph.D., July, 1997 - June, 1999.
- 6) Professor Ki-Young Lee, Ph.D., June, 1998 - September, 1998.
- 7) Won-Moon Choi, Ph.D. October, 1998 - September, 2000
- 8) Professor Jin-Ho Lee, Ph.D. March, 1999 - February, 2000
- 9) Hasoo Seong, Ph.D. November 1999 - November 2000
- 10) Yong Keun Chang, Ph.D., March 2000 - August 2000
- 11) Ghanashyam Acharya, Ph.D. March 2000 - February 2001
- 12) Jaehwi Lee, Ph.D. April 2000 - February 2004
- 13) Dukjoon Kim, Ph.D. January 2001- July 2002
- 14) Sang Cheon Lee, Ph.D. March 2001- December 2003
- 15) Hossein Omidian, Ph.D., March 2001- April 2002
- 16) Shi Cheng Yang, Ph.D., May 2001- June 2003
- 17) Tooru Ooya, Ph.D., September 2001- September 2002
- 18) Tomohiro, Konno, October, 2001
- 19) Seon Haeng Cho, Ph.D., October 2001- December 2002

- 20) Jong-Duk Kim, Ph.D. October 2001-September 2002
- 21) Byoung Yoon Kim, December 2001 - June 2002
- 22) Seung Rim Yang, July 2002 - December 2002
- 23) Jae Hyun Jeong, July 2003-December 2003
- 24) Susumu Kimura, Ph.D., August 2003-February 2005
- 25) Kang Moo Huh, Ph.D., December 2003 - October 2004
- 26) Jae Hyung Park, Ph.D., March 2004 - August 2005
- 27) Ji-Young Kim. M.S., June 2004 - January 2005
- 28) Sangyoun Lee, June 2004 – June 2006
- 29) Woo-Kyung Lee, Ph.D., July 2004 - February 2005
- 30) Dae Keon Choi, Ph.D., September 2004 - January 2006
- 31) Bong Sik Jeon, March 2005 - August 2005
- 31) Il Keun Kwon, Ph.D., March 2005 - February 2007
- 32) Woo Sun Shim, Ph.D., August 2005 - September 2006
- 33) Seonghoon Jeong, Ph.D., December 2005 - March 2006
- 34) Je Kyo Jeong, Ph.D. March 2006 - September 2006
- 35) Hatem Hegazy, March 2006 - September 2006
- 36) Sungwon Kim, Ph.D., August 2006 – September 2011
- 37) Xiaohong Wei, Ph.D., October 2006 - September 2007
- 38) Jong-Ho Kim, Ph.D. March 2007 - June 2008
- 39) Oju Jeon, Ph.D., April 2007 – March 2008
- 40) Yuuki Takaishi, October 2007 – September 2008
- 41) Ghanashyam Acharya, Ph.D. September 2007 –March 2011
- 42) Kyungmin Shin. August 2008 - July 2009
- 43) Kyeongsoon Park, Ph.D. August 2008 - July 2009
- 44) Nazgul Myzhanova, October - November 2008
- 45) Ayauzhan Tumabayeva, October - November 2008
- 46) Da-Won Oh. February 2009 - August 2009
- 47) Sungwon An. May 2009 - April 2010
- 48) Yeon Hee Yun, July 2009 - November 2009
- 49) Yoshio Kuno, Ph.D., October 2009 - September 2010
- 50) Professor Sung Soo Han, Ph.D. February 2010 - January 2011
- 51) Jung Min Cho, May 2010 - July 2011
- 52) Ki Young Choi, Ph.D.. August 2010 - July 2011
- 53) Byung Kook Lee, Ph.D., January 2011- August 2017
- 54) Yeon Hee Yun, Ph.D., May 2011 – January 2018
- 55) Professor Wenping Wang, Ph.D., November 2011 - November 2012
- 56) Byung-Dong Hahn, Ph.D., February 2012 – January 2013
- 57) Professor Yuhua Ma, M.S., March 2012 – February 2013
- 58) Professor Shengjiu Gu, Ph.D., March 2012 - September 2012

- 59) Professor Senlin Shi, Ph.D., June 2012 - May 2013
- 60) Professor Zhongqiong Qu, Ph.D., August 2012 -July 2013
- 61) Professor Nian-Ping Feng, Ph.D., August 2012 - July 2013
- 62) Professor Fei Qiu, Ph.D., September 2012 - August 2013
- 63) Jinhyun Hannah Lee, Ph.D., March 2013 - February 2014.
- 64) Professor Juqun Xi, Ph.D., August 2013 – August 2014
- 65) Professor Xueying Yan, Ph.D., February 2014 – January 2015
- 66) Yongjuan Shi, September 2014 - September 2015
- 67) Professor Xu Lu, Ph.D., October 2014 - October 2015
- 68) Andrew Otte, Ph.D., October 2014 – August 2019
- 69) Youngnam Lee, M.S., November 2014 - October 2016
- 70) Bong Kwan Soh, M.S., November 2014 – October 2019
- 71) Chang Geun Song, M.S., November 2014 - December 2015
- 72) Yahira Baez, Ph.D., November 2014 - October 2016
- 73) Professor Ming-Tao Zhang, PhD, December 2014 - August 2017
- 74) Seungman Park, Ph.D., December 2014 - November 2015
- 75) Ayauzhan Tumabayeva, M.S., January 2015 - December 2015
- 76) Professor Zhuangzhi Zhi, Ph.D., January 2015 - January 2016
- 77) Ellina Mun, Ph.D., November 2015 - September 2017
- 78) Daekoo Woo, M.S., October 2016 - August 2017
- 79) Haoying Yu, M.S., February 2017 - June 2017
- 80) Gwang Heum Yoon, M.S., October 2016 -
- 81) Dijia Yu, M.S., November 2017 - November 2018
- 82) Shweta Sharma, Ph.D., February 2018 -
- 83) Farrokh Sharifi, Ph.D., August 2018 -

Manuscript Reviews for Journals

ACS Advanced Chemistry Series
 Acta Anatomica
 Analytical Chemistry
 American Journal of Pathology
 American Journal of Transplantation
 Bioconjugate Chemistry
 Biomacromolecules
 Biomaterials
 Biotechnology and Bioengineering
 Colloids and Surfaces
 Computational and Theoretical Polymer Science
 CRC Critical Reviews
 Eur. J. Pharmaceutical Sci.
 Eur. J. Pharmaceutics & Biopharmaceutics
 European Polymer Journal
 Fundamental and Applied Toxicology
 IEEE Transaction on Biomedical Engineering

International Journal of Cancer
International Journal of Pharmaceutics
Journal of Adhesion
Journal of Applied Polymer Science
Journal of American Chemical Society
Journal of Bioactive and Compatible Polymers
Journal of Biomaterials Science-Polymer Edition
Journal of Biomedical Materials Research
Journal of Colloid and Interface Science
Journal of Controlled Release
Journal of Drug Targeting
Journal of Membrane Science
Journal of Pharmaceutical Science
Journal of Physical Chemistry. Letters Section
Journal of Polymer Science. Part A: Polymer Chemistry
Langmuir
Macromolecules
Molecular Therapy/Genomics
NanoLetters
Nature Biotechnology
Nature Nanotechnology
Polymer
Pharmaceutical Development and Technology
Pharmaceutical Research
PharmSciTech
Proceedings of the National Academy of Sciences, USA
Reactive and Functional Polymers
Scanning Microscopy
Separation Science and Technology
Trends in Polymer Science

EXHIBIT F

1 UNITED STATES DISTRICT COURT

2 DISTRICT OF DELAWARE

3 -----x

4 Par PHARMACEUTICAL, INC.,

Par STERILE PRODUCTS, LLC and

5 ENDO Par INNOVATION COMPANY, LLC,

6 Plaintiffs,

Civil Action No.

7 -against-

18-823-CFC

8 EAGLE PHARMACEUTICALS,

9 Defendant.

10 -----x

11 February 11, 2019

9:16 a.m.

12
13
14
15
16
17 Videotaped Deposition of DR. LEONARD J. CHYALL,
18 Ph.D., taken by Plaintiff, pursuant to Notice, at
the offices of Kirkland & Ellis, LLP, 601
19 Lexington Avenue, New York, New York, before
William Visconti, a Shorthand Reporter and Notary
20 Public within and for the State of New York.
21
22
23
24
25

1 things?

2 MR. LASKY: Objection to the form,
3 argumentative.

4 A. I have expertise in many things,
5 that is true.

6 Q. You're not registered to practice
7 before the U.S. Patent and Trademark Office,
8 correct?

9 A. That's correct.

10 Q. You're not a lawyer; correct?

11 A. No.

12 Q. You're not an expert in patent
13 law; correct?

14 A. No.

15 Q. You're not an expert in patent
16 prosecution, correct?

17 A. Correct.

18 Q. Have you ever been a Patent
19 Examiner?

20 A. No.

21 Q. Are you familiar with the training
22 every Patent Examiner receives?

23 A. I have some familiarity with that,
24 yes.

25 Q. The patent law concepts and rules

C E R T I F I C A T E

STATE OF NEW YORK)

: ss.

COUNTY OF NEW YORK)

I, WILLIAM VISCONTI, a Shorthand Reporter and
Notary Public within and for the State of New York,
do hereby certify:

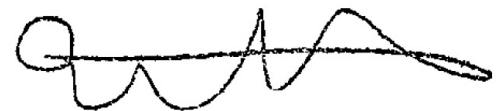
That prior to being examined, the witness named in
the foregoing deposition was duly sworn to testify the truth,
the whole truth, and nothing but the truth;

That said deposition was taken down by me in
shorthand at the time and place therein named and
thereafter reduced by me to typewritten form and that the
same is a true, correct, and complete transcript of said
proceedings.

Before completion of the deposition, review of the
transcript [X] was [] was not requested. If requested,
any changes made by the deponent (and provided to the
reporter) during the period allowed are appended hereto.

I further certify that I am not interested in the
outcome of the action.

Witness my hand this 25th day of 2020.



WILLIAM VISCONTI

EXHIBIT G

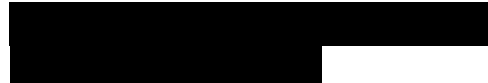
**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

PAR PHARMACEUTICAL, INC., PAR
STERILE PRODUCTS, LLC, and ENDO
PAR INNOVATION COMPANY, LLC,
Plaintiffs,

v.

EAGLE PHARMACEUTICALS INC.,
Defendant.

C.A. No. 18-00823-CFC



REPLY EXPERT REPORT OF KINAM PARK, PH.D.

efficacy and shelf-life. *See, e.g.*, Kannan Dep. 187:22–188:22; Vandse Dep. 254:16–22; Sanghvi Dep. 146:21–147:5, 148:14–149:8, 150:13–18, 151:3–22.

25. In addition, Dr. Kirsch's assertion that [REDACTED] is simply wrong. Kirsch Rebuttal ¶ 168–69. Dr. Kirsch relies on [REDACTED] But even Dr. Kirsch admits [REDACTED] *See, e.g.*, AR3-VASO-0000012; Kirsch Rebuttal ¶¶ 146, 151, 173, 178. Dr. Kirsch's reliance on [REDACTED] If Dr. Kirsch is right that [REDACTED] then this further confirms that information about the narrower, optimized pH ranges in the prior art, as seen with Pitressin® and Vasopressin®, were material to the patentability of Par's patents, despite being withheld by the inventors who were aware of it.

26. I note that other researchers also sought to prepare stable formulations of vasopressin using particular pH targets, contrary to Dr. Kirsch's argument that [REDACTED] For example, prior art Lithuanian Patent No. 4487 (PAR-VASO_0233012–22) teaches a target pH range of 3.80 to 3.95 in the manufacture of a vasopressin injection composition. PAR-VASO_0233014. This is a relatively narrow pH target, encompassing the claimed pH values, that evidences work to optimize the pH-dependent stability of vasopressin formulations.

exceptional or large in terms of the formulation process. As a result, a POSA would not expect significant differences in formulation properties across such small changes. Indeed, Dr. Kirsch himself argues that [REDACTED]

[REDACTED] Kirsch Rebuttal ¶ 348.

37. Furthermore, if Dr. Kirsch is correct, [REDACTED]
[REDACTED] Instead, as I explained in my Opening Report and Dr. Kirsch does not dispute, the inventors only identified disclosures of the full range of 2.5 to 4.5 in the prior art which, according to Dr. Kirsch, [REDACTED]
[REDACTED] Kirsch Rebuttal ¶ 176. Dr. Kirsch's assertion that [REDACTED]
[REDACTED] Kirsch Rebuttal ¶ 178, further confirms that the properties of those products were material to the patentability of the claims before the patent office, as this prior art undermines the inventors' criticality argument that the claimed pH range demonstrates unexpected and surprising stability over the prior art.

38. Further undercutting Dr. Kirsch's contention is [REDACTED]
[REDACTED] Throughout his report, Dr. Kirsch
[REDACTED]
[REDACTED]

See, e.g., Kirsch Rebuttal ¶ 182. As I explained at length in my Opening Report, however, POSAs knew that pH is typically the most important variable for peptide stability. *See, e.g.*, Park Opening ¶¶ 52–54, 345, 351–52. Thus, a POSA would have known that pH is a critical parameter to control and would have been motivated to find the stable value, even if acceptable products had been made and sold in the past.

51. As noted above, Dr. Kirsch also [REDACTED]

[REDACTED] *See, e.g.*, Kirsch Rebuttal ¶ 191. [REDACTED]

[REDACTED] Therefore, according to Dr. Kirsch's own analysis, [REDACTED]
[REDACTED]
[REDACTED]

3. There Are No Unexpected Results

52. Dr. Kirsch also [REDACTED]

[REDACTED]
[REDACTED]
Kirsch Rebuttal ¶ 186. This evidence, however, falls well short of showing any unexpected stability for the claimed pH values over the prior art. In addition, I rely on Dr. Chyall's Opening and Reply Reports as further demonstrating why Dr. Kirsch has not established criticality.

53. I understand that to demonstrate that a value within a known range is critical, surprising and unexpected results must be shown across the entire claimed range, and must also establish an advantage over all values outside the claimed range. Dr. Kirsch does not address the fact that formulations with pH values that are outside of the claimed pH values can readily meet the stability and degradation limitations of the asserted claims. [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

¹ *See, e.g.*, EAGLEVAS0047284-87; EAGLEVAS0047288; EAGLEVAS0047291; EAGLEVAS0047294-97; EAGLEVAS0047298-300; EAGLEVAS0047301; EAGLEVAS0047304-10; EAGLEVAS0047311-17;

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Compare *supra* n.1, with PAR-VASO_0024408–21, and PAR-VASO_0050219–319. Under these circumstances, the pH values recited by the claims cannot be unexpectedly stable and critical over the values of the prior art. This further undermines Dr. Kirsch’s assertion that [REDACTED]

[REDACTED] To the extent that the testing presented by the inventors during prosecution and in the patent examples showed an advantage of the claimed pH range, testing of the prior art Vasostrict® formulation [REDACTED] compared to the reformulated Vasostrict® would have undermined that conclusion.

54. I also note that at least one batch of prior art Vasostrict®, as discussed herein and in my Opening Report, had a pH that increased to pH 3.8 during its shelf life. Dr. Kirsch argues

[REDACTED]

[REDACTED] Kirsch Rebuttal ¶¶ 152–54. [REDACTED]

[REDACTED]

EAGLEVAS0047318–24;	AMRIVAS0117010–13;	AMRIVAS0117014–17;	AMRIVAS0117018–21;
AMRIVAS0117022–26;	AMRIVAS0117026–29;	AMRIVAS0117030–33;	AMRIVAS0117034–37;
AMRIVAS0117038–41;	AMRIVAS0117042–45;	AMRIVAS0117046–49;	AMRIVAS0117050–53;
AMRIVAS0117054–57;	AMRIVAS0117058–61;	AMRIVAS0117062–65;	AMRIVAS0117066–69;
AMRIVAS0117072–75;	AMRIVAS0117076–79;	AMRIVAS0117084–87;	AMRIVAS0117088–91;
AMRIVAS0117096–99.			

[REDACTED]

[REDACTED]

[REDACTED] Thus, this same analysis applies to the impurity limitations of the '209 and '785 patents.

150. Dr. Kirsch undercuts his infringement analysis by stating that [REDACTED] with regard to impurities. Kirsch Rebuttal ¶ 158. At the same time, Dr. Kirsch relies only on [REDACTED]

[REDACTED]

[REDACTED]

VI. THE WITHHELD PRIOR ART REFERENCES AND INFORMATION ARE MATERIAL

151. I understand that a preponderance of the evidence standard is applied by the examiner during the prosecution of applications before the Patent and Trademark Office. Furthermore, I understand that the burden of proving infringement is also a preponderance of the evidence.

A. The False Declarations Regarding the April 2014 Vasostrict® Label Are Material

152. As set forth in my opening report, the April 2014 Vasostrict® Label was excluded as prior art during prosecution of the '239 patent (and later during prosecution of the remaining patents-in-suit) solely because of the Kannan and Bonomi-Huvala Declarations, which represented that Vinayagam Kannan and Matthew Kenney invented the subject matter of the April 2014 Vasostrict® Label cited by the Examiner in her rejection. These Declarations were false, however, and the inventors did not invent that subject matter.

153. Dr. Kirsch recognizes that the Kannan and Bonomi-Huvala Declarations were filed and resulted in removal of the rejection over the April 2014 Vasostrict® Label. Kirsch

Rebuttal ¶¶ 289–90. Dr. Kirsch does not, however, dispute that those declarations were false and that the inventors did not invent the relevant subject matter of the April 2014 Vasostrict® Label. The Declarations led the Examiner to remove a final rejection of the pending claims over the April 2014 Vasostrict® Label. In addition, because the '209, '526, and '785 patents are each continuations-in-part of the '239 patent and named both of the inventors of that patent, those false declarations also tainted the prosecution of the asserted patents as the Examiner believed she could not rely on the April 2014 Vasostrict® Label as prior art. The Declarations were material to the prosecution of those patents as well.

154. To the extent criticality is relevant to whether the April 2014 Vasostrict® Label is material prior art, I rely on the analysis set forth above, in my Opening Report, and in Dr. Chyall's Opening and Reply Reports and conclude that the inventors could not have shown criticality over this reference had it been relied on as prior art during prosecution.

1. '239 Patent

155. Because the Declarations were false, I understand that they are considered material to the prosecution of the '239 patent.

156. Dr. Kirsch's only argument as to why the April 2014 Vasostrict® Label was not material to the '239 patent claims is that [REDACTED]
[REDACTED] This argument is contradicted by the fact that the Examiner specifically found that the Label inherently disclosed the degradation products limitations of the all of the claims. PAR-VASO-0008327. The same reasoning that the Examiner applied to the specific degradation products levels would also apply to the broader degradation products limitation that Dr. Kirsch discusses. Therefore, if the Examiner had not been persuaded to disqualify the April 2014 Vasostrict® Label as prior art on false pretenses, the claims of the '239 patent as amended would not have issued.

157. Furthermore, Dr. Kirsch's [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED] Kirsch Rebuttal ¶ 409. Again, this statement is contradicted by the fact that Dr. Kirsch relies on just [REDACTED] [REDACTED] despite evidence from that and other batches to the contrary.

158. In addition, both Matthew Kenney, a named inventor, and Michelle Rennwald, a Par employee responsible for quality control and stability testing, testified [REDACTED]
[REDACTED]
Kenney Dep. 108:22–109:7; Rennwald Dep. 203:10–21. Thus, Dr. Kirsch's argument that [REDACTED]
[REDACTED]

159. Dr. Kirsch is incorrect regarding the conditions for the stability testing I cited. As I explained in my Opening Report, original Vasostrict® met the degradation products limitations initially as well as after at least three months of room temperature storage. *See, e.g.* PAR-VASO_0073585–609. Thus, I rely not just on refrigerated storage results for Vasostrict®, but also [REDACTED] Furthermore, to the extent the actual testing is relevant to the patentability of the '239 patent claims, not to mention [REDACTED] [REDACTED] as Dr. Kirsch asserts, then the inventors should have disclosed that information to the Examiner.

160. Dr. Kirsch's final argument regarding the timing of the degradation products limitation is inconsistent with the Examiner's findings and analysis. The Examiner found that the April 2014 Vasostrict® Label disclosed the other limitations of the independent claim,

including pH, as well as each of the dependent claim limitations directed to particular vasopressin degradation products by inherency. PAR-VASO-0008327. Dr. Kirsch does not explain how this Label can disclose inherently each of the specific degradation products at the proper time, to the satisfaction of Examiner, but not the degradation products limitation discussed by Dr. Kirsch here. Kirsch Rebuttal ¶ 409. While Dr. Kirsch [REDACTED] [REDACTED] he makes no attempt to perform the same evaluation of Eagle's ANDA product on infringement. There is also no basis to impose additional requirements beyond what the Examiner looked for to conclude that the prior art, excluded pursuant to the false declarations, would not have been material to the Examiner.

161. In addition, in the inherency findings the Examiner made in rejecting the pending claims over the April 2014 Vasostrict® Label, the Examiner also found the 0–2% degradation products limitation disclosed inherently by PPC. PAR-VASO-0008426. The same analysis necessarily applies to the disclosure of the April 2014 Vasostrict® Label, which recites a narrower pH range than PPC that also overlaps with that of the '239 patent claims. *Compare* PAR-VASO-0008426, *with* PAR-VASO-0008327.

162. Although unclear in Dr. Kirsch's report, the April 2014 Vasostrict® Label's pH of 3.4 to 3.6, would have anticipated the broader pH range of 3.5 to 4.1 as set forth in the '239 patent claims. Dr. Kirsch states that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Kirsch Rebuttal ¶ 404. This is incorrect because, unlike with the PPC,

the inventors would not have been able to show criticality over the narrower overlapping range in the Label, which was anticipatory.

2. Asserted Patents

163. The April 2014 Vasostrict® Label was also material prior art with respect to the remaining patents-in-suit because it would have prevented the issuance of asserted claims from each of those patents for the reasons set forth above.

164. As I note above, given Par's admissions about Eagle's ANDA product, there can be no dispute that the formulation described by the April 2014 Vasostrict® is within the scope of the asserted claims in view of Par's infringement allegations. If the April 2014 Vasostrict® Label does not disclose a formulation that expressly or inherently satisfies the composition limitations of the asserted patents, then [REDACTED] must also not meet those limitations and therefore cannot infringe.

165. Dr. Kirsch's Rebuttal Report confirms that [REDACTED]
[REDACTED]
[REDACTED] See, e.g., Kirsch Rebuttal ¶¶ 156–57, 178, 180, 182. In fact, Dr. Kirsch's obviousness arguments are largely centered on his point that [REDACTED]
[REDACTED] See e.g., Kirsch Rebuttal ¶¶ 166–69, 177–79. To the extent this is true, such prior art should have been available to the Examiner and not excluded based on the false declarations. An “optimized” prior art formulation that abuts (for the '209 and '785 patents) or is close (for the '526 patent) to the claimed values would be important to the Examiner in evaluating the claims, particularly when Par was claiming that the pH values as claimed were critical to stability.

166. Without consideration of the pH of Vasostrict® as taught by its Label, the information before the Examiner consisted only of a pH range that Dr. Kirsch contends a POSA would believe was not optimized, i.e., pH 2.5–4.5. Therefore, per Dr. Kirsch’s analysis, it would have appeared to the Examiner that the named inventors were the only ones to have tried to undertake the optimization the pH of vasopressin, and otherwise POSAs had little to no knowledge of the pH-dependent stability of vasopressin. Without such knowledge, the alleged stability benefits of the claimed pH were clearly more likely to have been considered unexpected and critical compared to the broader range in the art. But when the Label is considered, it is clear that vasopressin formulations had already been stabilized through pH investigations, and a region abutting or close to the claimed values found to be optimum. Proving that the claimed pH ranges were critical would have required significantly more evidence than was actually provided to the Examiner, and given that Dr. Kirsch has identified no such evidence, it is apparently unavailable. Thus, contrary to Dr. Kirsch’s opinions, Kirsch Rebuttal ¶ 404, the April 2014 Vasostrict® Label is material prior art that was significantly closer to the asserted claims than the PPC reference, and in any event would have undermined the inventors’ criticality arguments.

B. Pitressin®

167. As explained above and in my Opening Report, Pitressin® was not only targeted to [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

168. In addition, the Examiner already found that similar prior art, including PPC and the April 2014 Vasostrict® Label, inherently disclosed the impurity limitations of the claims,

and Pitressin® would similarly have been found to do so, a conclusion for which Dr. Kirsch has no contradictory evidence.

169. The Examiner also found it would have been obvious to refrigerate a vasopressin formulation for the similar PPC reference, and a similar conclusion would also have applied to Pitressin®.

170. To the extent these findings would not have been made by the Examiner, Pitressin® still would have precluded the issuance of the asserted claims based on the same invalidity analysis set forth above. Furthermore, Dr. Kirsch's Rebuttal Report suggests that even more information should have been disclosed to the Examiner, including impurity testing, to show that the prior art product met the impurity limitations that Par claims could only be achieved with the claimed formulation. Dr. Kirsch does not indicate that this information was provided to the Examiner.

171. Dr. Kirsch argues that [REDACTED]

[REDACTED] If it that were true, as with the original Vasostrict® formulation, it should have been disclosed to the Examiner, as it would be closer prior art that what the Examiner had before her. The PPC reference, before the Examiner, disclosed what Dr. Kirsch contends [REDACTED]

[REDACTED] Without disclosing the pH of Pitressin®, the inventors suggested that no attempts had been made to optimize the pH of Pitressin®, and the inventors' work was truly beneficial. The inventors could not have made such assertions, which were critical to allowance of the claims, if the complete formulation of the prior art Pitressin® product had been disclosed.

C. Vasostrict®

172. For similar reasons, the Vasostrict® testing discussed in my Opening Report and above was material to patentability of the asserted claims. Indeed, Dr. Kirsch admits that [REDACTED] was reflective of the product in the April 2014 Vasostrict® Label, Kirsch Rebuttal ¶ 423–24, a formulation that was specifically found by the Examiner to be material prior art and that the inventors avoided only through a false declaration. For the same reasons discussed above, that Vasostrict® product and would have invalidated the asserted claims.

173. Further, as noted, the Examiner already found during prosecution of the '239 patent that this formulation inherently disclosed the very impurities and their amounts that count towards the ranges in the '209 and '526 patent. Therefore, Vasostrict® at this pH also would have been found to inherently disclose the impurity limitations, as the April 2014 Vasostrict® Label and [REDACTED] are, to Dr. Kirsch, the same. *See, e.g.*, Kirsch Rebuttal ¶ 423.

174. In addition, to the extent that the measured impurity levels of Vasostrict® are important to patentability, as Dr. Kirsch repeatedly suggests, then that data should have been disclosed to the Examiner. Dr. Kirsch does not indicate that it was.

D. Response to Dr. Kirsch's Remaining '239 Patent Opinions

1. Pitressin®

175. Dr. Kirsch does not dispute that [REDACTED] Kirsch Rebuttal ¶¶ 412–417. In fact, [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] Kirsch Rebuttal ¶ 414.
Because, even according to Dr. Kirsch, [REDACTED]

[REDACTED] the inventors could not have salvaged patentability by resorting to criticality (or asserting that the claimed range had “good stability”).

176. Dr. Kirsch relies on the fact that [REDACTED]

[REDACTED] This argument is contradicted by the fact that the Examiner already found that PPC and the April 2014 Vasostrict® Label inherently disclosed this limitation as well as the related dependent limitations of those claims. This same exact reasoning applies to Pitressin®, which also discloses the same chemical components of the claims and, but for [REDACTED] is identical to the formulation in the April 2014 Vasostrict® Label. Therefore, if the Examiner had known about Pitressin®’s actual properties, this limitation would not have been found to confer patentability.

177. Furthermore, Dr. Kirsch contradicts himself by [REDACTED]

[REDACTED] As I have explained, I have evaluated whether Pitressin® as made and sold with BCN-sourced API satisfies the claims: I have looked to a stability study to show how these batches would behave over their shelf lives. Dr. Kirsch cannot now argue that this is somehow insufficient.

178. If the impurity results are important to whether Pitressin® invalidates the claims or not, then that data should have been disclosed to the Examiner during prosecution. Dr. Kirsch

does not even imply that such information was provided as part of a fulsome disclosure of the Pitressin® prior art.

179. In addition, Dr. Kirsch contends that [REDACTED]

[REDACTED] If that were true, then the inventors should have disclosed its pH to the Examiner.

2. Vasostrict®

180. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] PAR-VASO_0028328. Therefore, it satisfies the claims of the '239 patent and the inventors could not have avoided a rejection using criticality.

181. In addition, that batch would have been found to inherently disclose the limitations of the '239 patent under the Examiner's April 2014 Vasostrict® Label inherency analysis. Indeed, that prior art reference is the label for the same exact product, and Dr. Kirsch

[REDACTED]

[REDACTED] Kirsch Rebuttal ¶ 423. If degradation products testing were actually important to materiality, then it should have been disclosed to the Examiner.

VII. ADDITIONAL STABILITY DATA FURTHER ESTABLISHES THAT EAGLE'S ANDA PRODUCT DOES NOT INFRINGE THE ASSERTED CLAIMS

182. I understand that additional stability data for Eagle's ANDA product was recently made available.³ Contrary to Dr. Kirsch's infringement opinions, and consistent with my

³ See, e.g., AMRIVAS0117042-45; AMRIVAS0117046-49; AMRIVAS0117050-53; AMRIVAS0117054-57; AMRIVAS0117058-61; AMRIVAS0117062-65; AMRIVAS0117066-69; AMRIVAS0117070-71;

Dated: January 20, 2020

A handwritten signature in black ink, reading "Kinam Park". The signature is written in a cursive style with a large, looped "P".

Kinam Park, Ph.D.

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

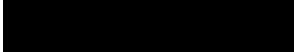
PAR PHARMACEUTICAL, INC.,)	
PAR STERILE PRODUCTS, LLC, and)	
ENDO PAR INNOVATION)	
COMPANY, LLC,)	
)	C.A. No. 18-823-CFC
Plaintiffs,)	
)	
v.)	
)	
EAGLE PHARMACEUTICALS INC.,)	
)	
Defendant.)	

EXHIBIT 15.2.2

**DEFENDANT'S OPPOSITION TO
PLAINTIFFS' MOTION *IN LIMINE* NO. 2**

Par asks the Court to parse through 100+ paragraphs of legitimate expert opinion to strike unidentified portions allegedly directed to “intent, motive, and state of mind.” The Court need not do so. Eagle agrees its experts will not testify to the ultimate questions of intent, motive, and state of mind.

But to the extent Par seeks blanket exclusion of the cited paragraphs, it overreaches. Even Par’s cited cases make clear that experts may testify to materiality of prior art and information withheld during prosecution and facts from which intent to deceive may be inferred. In *Medicines Co. v. Mylan Inc.*, an expert was precluded “from opining on what the Patent Office Examiner would have done or thought had she been given different information,” but was permitted to “opine as to what he believes would have been material to the patent examiner” and “discuss and disclose facts, without opining on what the Patent Office Examiner would have done or thought.” 2014 WL 1516599, at *4–5 (N.D. Ill. Apr. 17, 2014). Another expert was precluded from “testify[ing] as to whether the inventors actually had a specific intent to deceive the Patent Office,” but permitted to “identify certain facts from the file history and record to support an inference that the applicants acted with intent to deceive.” *Medicines Co. v. Mylan Inc.*, 2014 WL 1758135, at *5 (N.D. Ill. May 2, 2014). Par’s other cited cases—many outside the inequitable conduct context—are not contrary.

Viewed in context, the paragraphs Par identifies¹ either merely describe what the expert was asked to opine on,² or comprise proper opinions on materiality and/or identification of facts supporting intent to deceive, including:

- facts from the file histories and opinions on such;³
- facts from Par's documents and inventor depositions and opinions on such;⁴
- opinions on materiality of prior art improperly withheld or disqualified,⁵ including whether the inventors could have established criticality of the claimed pH over the withheld/disqualified references;⁶ and

¹ Citations are to the exhibits in Par's Motion.

² Ex. A ¶¶9; Ex. E ¶377.

³ Ex. D ¶¶243-45, 248; Ex. E ¶¶388, 390; Ex. G ¶¶152-53, 156, 161, 168-69, 173, 176, 181.

⁴ Ex. A ¶113; Ex. B ¶120; Ex. D ¶246; Ex. E ¶¶410-11.

⁵ Ex. D ¶¶47, 247, 249-53 (materiality for claimed clinical elements); Ex. E ¶¶379-92, 409-16, 420-28 (materiality for claimed formulation elements), 404-08, 417-19 (closeness of prior art); Ex. G ¶¶25, 37 (response to Par's expert on motivation to optimize pH), 155-81 (response to Par's expert on materiality).

⁶ Ex. A ¶¶83, 90 (criticality cannot overcome anticipation by April 2014 Vasostrict® Label), 102, 111-12 (data in declarations do not support criticality), 114, 118, 121, 124-25, 127, 130-32, 136, 141-46 (discussing data), 149, 155-56; Ex. B ¶¶12, 19, 21 (response to Par's expert); Ex. E ¶¶393-95 (agreeing with Dr. Chyall on criticality), 396 (noting inventors never compared data submitted for criticality to stability data on the April 2014 Vasostrict® formulation), 397 (discussing representations to FDA undermining criticality), 401-03 (discussing file history statements undermining criticality); Ex. G ¶53.

- opinions on materiality of other withheld information undermining the inventors' criticality assertions.⁷

This is all legitimate expert testimony that should not be excluded. *See Medicines Co.*, 2014 WL 1516599, at *4–5; *Medicines Co.*, 2014 WL 1758135, at *5; *ART+COM Innovationpool GmbH v. Google Inc.*, 155 F. Supp. 3d 489, 510 (D. Del. 2016) (“Dr. Goodchild’s technical testimony is helpful to the determination of whether Mr. Mayer’s declaration to the PTO was accurate when made.”); *Sonos, Inc. v. D&M Holdings Inc.*, 297 F. Supp. 3d 501, 511, 513 (D. Del. 2017) (“[T]echnical experts are not forbidden from offering opinions on technical matters that lead them to particular conclusions that bear on ultimate issues in the case,” including, for example, anticipation, obviousness, and invalidity).

Par’s motion should be denied.

⁷ Ex. A ¶¶84, 170 (opining “[t]he withholding of the normalized data was particularly significant,” given inventor representations to PTO), 177, 186 (discussing withheld normalized data and pH study undermining criticality); 188 (opining data was “clearly material”), 194-95 (discussing significance of data variability); Ex. B ¶¶60 (disagreeing with Par’s expert on materiality/criticality), 90 (noting inventors “did not account for all material variability present in the data”), 96 (responding to Par’s expert’s opinion that [REDACTED]”); Ex. E ¶¶398-400 (discussing inventors’ pH study withheld from PTO), 415 (discussing withheld Pitressin® data refuting criticality), 429-34 (agreeing with Dr. Chyall that withheld normalized data undermines criticality).

Date: May 11, 2020

POTTER ANDERSON & CORROON LLP

By: /s/ Bindu A. Palapura

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CERTIFICATION OF COMPLIANCE

The foregoing document complies with the type-volume limitation of this Court's March 2, 2020 form Scheduling Order For All Cases where Infringement is Alleged. The text of this brief, including footnotes, was prepared in Times New Roman, 14 point. According to the word processing system used to prepare it, the brief contains 735 words, excluding the case caption, signature block, table of contents and table of authorities.

Date: May 11, 2020

/s/ Bindu A. Palapura
Bindu A. Palapura (Bar No. 5370)

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**


<p>PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC and ENDO PAR INNOVATION COMPANY, LLC,</p> <p>Plaintiffs,</p> <p>v.</p> <p>EAGLE PHARMACEUTICALS INC.,</p> <p>Defendant.</p>	<p>C.A. No. 18-cv-823-CFC</p> <p></p>
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EXHIBIT 15.2.3

**PLAINTIFFS' REPLY TO PLAINTIFFS' MOTION IN LIMINE #2 TO
PRECLUDE STATE OF MIND TESTIMONY BY EAGLE'S EXPERTS**

Eagle acquiesces to Par’s requests regarding state of mind testimony: “Eagle agrees its experts will not testify to the ultimate questions of intent, motive, and state of mind.” Mot.Opp. at 1. But Eagle misapprehends the scope of state of mind testimony. For inequitable conduct, “the analysis of th[e] *but-for* materiality requirement is from the perspective of the PTO.” *See Ohio Willow Wood Co. v. Alps S., LLC*, 735 F.3d 1333, 1345 (Fed. Cir. 2013). “In other words, the examiner’s perspective controls.” *Kranos IP Corp. v. Riddell, Inc.*, 334 F. Supp. 3d 907, 913 (N.D. Ill. 2018). Expert opinions about materiality necessarily go to the Examiner’s state of mind, and thus are precluded: “[t]he law of this district [Delaware] is clear that experts in patent cases may not opine ... whether certain information was material to a pending patent application....” *Brigham & Women’s Hosp. Inc. v. Teva Pharms. USA, Inc.*, No. 08-464, 2010 WL 3907490, at *2 (D. Del. Sept. 21, 2010).

Further, Eagle asserts that in addition to its now-admittedly improper opinions on intent, the cited paragraphs include proper opinions regarding the “facts from which intent to deceive may be inferred.” Mot.Opp. at 1. But that assertion is irrelevant to this MIL, because it goes beyond what Par seeks to preclude.

Accordingly, the Court should preclude Eagle's experts' state of mind opinions (identified by paragraph in Par's motion), including without limitation opinions on state of mind relating to materiality and intent.

Dated: May 11, 2020

Respectfully submitted,

FARNAN LLP

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CERTIFICATION OF COMPLIANCE

The foregoing document complies with the type-volume limitation of this Court's March 2, 2020 form Scheduling Order For All Cases where Infringement is Alleged. The text of this brief, including footnotes, was prepared in Times New Roman, 14 point. According to the word processing system used to prepare it, the brief contains 241 words, excluding the case caption, signature block, table of contents and table of authorities.

/s/ Brian E. Farnan

Brian E. Farnan (Bar No. 4089)

Dated: May 11, 2020

EXHIBIT 16.1

EAGLE'S MOTION *IN LIMINE* NO. 1

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**


PAR PHARMACEUTICAL, INC.,)	
PAR STERILE PRODUCTS, LLC, and)	
ENDO PAR INNOVATION)	
COMPANY, LLC,)	
)	C.A. No. 18-823-CFC
Plaintiffs,)	
)	
v.)	
)	
EAGLE PHARMACEUTICALS INC.,)	
)	
Defendant.)	

EXHIBIT 16.1.1

**DEFENDANT'S MOTION *IN LIMINE* NO. 1
TO PRECLUDE TESTIMONY REGARDING
MATTERS ON WHICH PAR CLAIMED PRIVILEGE**

Eagle moves to preclude Par from offering testimony at trial on certain matters relevant to Eagle's unenforceability counterclaims over which Par claimed privilege in discovery. *See Andover Healthcare, Inc. v. 3M Co.*, No. 13-843-LPS, 2016 WL 6404111, at *2 (D. Del. Oct. 27, 2016) (excluding testimony on topics for which party asserted privilege during Rule 30(b)(6) deposition).

Eagle asserts that Par's named inventors, prosecuting attorney and regulatory officer committed inequitable conduct during prosecution of the Patents-in-Suit and parent '239 patent by, *inter alia*, (1) submitting declarations falsely claiming the named inventors invented "all the subject matter" in the label for Par's original Vasostrict® relied on by the Examiner to reject the pending claims; (2) withholding material information about the pH of prior art vasopressin formulations; and (3) withholding information that undermines the inventors' claims to criticality of the pH ranges recited in the asserted claims. (*See* D.I. 136 ¶¶ 60-157, 194-353, 427-34, 439-42.)

During depositions, [REDACTED]

[REDACTED] But it is well-established that a party may not use privilege "as both a sword and a shield." *Andover*, 2016 WL 6404111, at *2; *see also Berkeley Inv. Grp., Ltd. v. Colkitt*, 455 F.3d 195, 222 (3d Cir. 2006). A party cannot "divulge whatever information is favorable to the client's position and assert the privilege to preclude disclosure of the detrimental facts." *Princeton Digital*

Image Corp. v. Office Depot Inc., No. 13-239-LPS, 2017 WL 3264068, at *2 (D. Del. Aug. 1, 2017) (internal marks omitted).

For example, Par's attorneys instructed witnesses not to answer, or the witnesses invoked privilege and refused to answer, questions regarding: [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Allowing Par to present evidence, testimony or argument on these matters at trial would allow Par to do just that. Par should be precluded from doing so. *See Lucent Techs., Inc. v. Newbridge Networks Corp.*, 168 F. Supp. 2d 181, 262 (D. Del. 2001) (upholding exclusion of facts subject to privilege); *see also* William A. Schwarzer, et al., *Federal Civil Procedure Before Trial*, ¶ 11:37, at 11-29 (2000) (“[W]here the party claiming privilege during discovery wants to testify at the time of trial, the court may ban that party from testifying to matters claimed to be privileged.”).

[REDACTED]

[REDACTED]

[REDACTED]

Date: May 11, 2020

POTTER ANDERSON & CORROON LLP

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CERTIFICATION OF COMPLIANCE

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Date: May 11, 2020

/s/ Bindu A. Palapura
Bindu A. Palapura (Bar No. 5370)

EXHIBIT 1

REDACTED

EXHIBIT 2

REDACTED

EXHIBIT 3

REDACTED

EXHIBIT 4

REDACTED

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**


<p>PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC and ENDO PAR INNOVATION COMPANY, LLC,</p> <p>Plaintiffs,</p> <p>v.</p> <p>EAGLE PHARMACEUTICALS INC.,</p> <p>Defendant.</p>	<p>C.A. No. 18-cv-823-CFC</p> <p></p>
--	---

EXHIBIT 16.1.2

**PLAINTIFFS' OPPOSITION TO DEFENDANT'S MOTION *IN LIMINE*
NO. 1 TO PRECLUDE TESTIMONY REGARDING MATTERS
ON WHICH PAR CLAIMED PRIVILEGE**

Par does not intend to use privilege as both a sword and shield, and will not proffer testimony at trial concerning communications over which it asserted privilege during depositions. Eagle moves for preclusion of six categories of testimony, some of which are privileged and were subject to appropriate instructions, but Eagle paints with too broad a brush and sweeps in subjects unrelated to any privilege claim. Thus, Eagle's motion is an "extravagant demand at odds with the generally understood contours of the attorney-client privilege" and should be denied. *Ampex Corp. v. Eastman Kodak Co.*, 04-1373-KAJ, 2006 WL 1995140, at *2 (D. Del. July 17, 2006). As this is a bench trial, the parties would be best served by dealing with any pertinent objections at trial.

During depositions, counsel drew a careful line between privileged attorney-client communications and non-privileged matters, such as [REDACTED] [REDACTED] and Eagle never challenged Par's assertions of privilege. Par's witnesses answered numerous questions regarding, for example, Eagle's inequitable conduct theories, many of which are included in the thousands of lines of deposition testimony Eagle has designated for trial.

The majority of testimony Eagle cites is from the deposition of Craig Kenesky, the prosecuting attorney. Ex. 1. Kenesky is not on Par's trial witness list, and Par has not designated his testimony for trial (but has counter-designated

testimony responsive to testimony Eagle itself intends to use), so as a practical matter, there is no testimony from Kenesky to preclude. Similarly, Par does not intend to offer evidence relating to [REDACTED]

[REDACTED] Hence, Eagle's enumerated topics 1, 2, 4, and 5 are not truly in dispute.

Eagle's topics 3 and 6, however, are overbroad, and include non-privileged subject matter about which Eagle did question Par witnesses during depositions.

Regarding topic 3— [REDACTED]

[REDACTED] [REDACTED] [REDACTED] [REDACTED]
[REDACTED] [REDACTED] [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED] *See, e.g.*, Ex. A (Kannan Dep.) 254:19-264:16; Ex. B (Kenney Dep.) 28:14-44:15. The only objected-to testimony from either inventor that Eagle cites as a basis for preclusion is [REDACTED]

[REDACTED] Mot. at 2 n.3 (citing Mot. Ex. 2 at 269:12-270:2). That is different from the stated topic, and Par does not intend to elicit testimony about [REDACTED]

Regarding topic 6— [REDACTED]

[REDACTED] [REDACTED] the only objected-to testimony Eagle cites [REDACTED]
[REDACTED] [REDACTED]

██████ Mot. at 3 n.6. Par does not intend to elicit testimony about ██████

██████ ██████████ Beyond that, Eagle's preclusion request is overbroad. There is no basis, for example, to preclude ██████

██

██

██

Eagle's cases do not support the blanket exclusions it seeks. In *Andover*, although defendant was not permitted to present testimony about developing its product to avoid infringement, a topic over which it specifically asserted privilege, its fact witnesses were permitted to "explain how it intended to develop, and believes it succeeded in developing, a product without crystallinity" that would avoid infringement. *Andover Healthcare, Inc. v. 3M Co.*, 13-843-LPS, 2016 WL 6404111, at *2 (D. Del. Oct. 27, 2016). Similarly, here, the inventors answered questions about, and should be permitted to testify concerning, what they believed they invented, and what they meant by their declarations.

In contrast to *Berkeley*, this is not a case where Par is saying the inventors relied on the advice of counsel and then is refusing to reveal what that advice was. *Berkeley Inv. Grp., Ltd. v. Colkitt*, 455 F.3d 195, 221 n.24 (3d Cir. 2006). *Lucent* is even further off-point; the party asserting privilege in that case agreed to redact jury trial exhibits, then complained that excluding testimony related to the redacted

portions was improper. *Lucent Techs., Inc. v. Newbridge Networks Corp.*, 168 F. Supp. 2d 181, 261-62 (D. Del. 2001).

The Court should deny Eagle's motion, and deal with any objections to specific questions if and when they arise at trial.

Dated: May 11, 2020

Respectfully submitted,

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CERTIFICATION OF COMPLIANCE

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/s/ Brian E. Farnan

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Dated: May 11, 2020

EXHIBIT A

REDACTED

EXHIBIT B

REDACTED

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**


PAR PHARMACEUTICAL, INC.,)	
PAR STERILE PRODUCTS, LLC, and)	
ENDO PAR INNOVATION)	
COMPANY, LLC,)	
)	C.A. No. 18-823-CFC
Plaintiffs,)	
)	
v.)	
)	
EAGLE PHARMACEUTICALS INC.,)	
)	
Defendant.)	

EXHIBIT 16.1.3

**DEFENDANT’S REPLY IN SUPPORT OF MOTION *IN LIMINE* NO. 1
TO PRECLUDE TESTIMONY REGARDING
MATTERS ON WHICH PAR CLAIMED PRIVILEGE**

Having shielded presumably unfavorable testimony from discovery via privilege, Par now wants to selectively introduce helpful testimony on the same topics. The Court should not permit it.

As one example, evidence establishes that [REDACTED]

[REDACTED] (D.I. 136, ¶¶60-157; Mot. Ex. 2, 250:6-12.) Par apparently now intends to [REDACTED]

[REDACTED] (PTO Ex. 2, ¶236.) [REDACTED]

[REDACTED] (Mot. Ex. 2, 269:12-270:2.) Par likewise [REDACTED]

[REDACTED] (Mot. Ex. 1, 136:6-138:9, 147:24-148:17.) Par's attempt to introduce only helpful testimony, while blocking discovery, is exactly what the sword-and-shield doctrine is intended to prevent.

Par's argument that preclusion is limited to the objected-to questions or specific underlying communications is incorrect. Fairness demands it extend to the broader "subject matter" the privilege assertion foreclosed the opposing party from reasonably investigating. *Feduniak v. Old Republic Nat'l Title Co.*, 2015 WL 13439778 at *2-3 (N.D. Cal. Apr. 24, 2015) (excluding testimony on broad topics of privilege assertions); *see also Andover Healthcare Inc. v. 3M Co.*, 2016 WL

6404111 at *2 (D. Del. Oct. 27, 2017) (same). Because Par shielded potentially unfavorable testimony regarding Eagle's identified topics, Par should be precluded from selectively presenting favorable testimony on those topics.

Date: May 11, 2020

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Date: May 11, 2020

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EXHIBIT 16.2

EAGLE'S MOTION *IN LIMINE* NO. 2

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**


PAR PHARMACEUTICAL, INC.,)	
PAR STERILE PRODUCTS, LLC, and)	
ENDO PAR INNOVATION)	
COMPANY, LLC,)	
)	C.A. No. 18-823-CFC
Plaintiffs,)	
)	
v.)	
)	
EAGLE PHARMACEUTICALS INC.,)	
)	
Defendant.)	

EXHIBIT 16.2.1

**DEFENDANT'S MOTION *IN LIMINE* NO. 2 TO PRECLUDE TESTIMONY
REGARDING SPECIFIC INTENT TO INDUCE INFRINGEMENT**

Eagle moves to preclude Par from offering expert testimony regarding alleged “specific intent” by Eagle to induce infringement because Par failed to timely disclose any theory or expert opinion on that issue.

To prove inducement, Par must prove Eagle has the “specific intent” to induce others to infringe. *Takeda Pharm. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015). This requires “more than just intent to cause the acts that produce direct infringement,” but instead “an affirmative intent to cause direct infringement.” *DSU Med. Corp. v JMS Co.*, 471 F.3d 1293, 1306 (Fed Cir. 2006).

Par must therefore prove Eagle has an “affirmative intent” to induce use of a vasopressin formulation with a pH of 3.8 (’526 patent), or 3.7-3.9 (’209 or ’785 patents), [REDACTED]
[REDACTED] (E.g., Ex. 1 at Ex. A at 2.)

But Par did not timely disclose any evidence on intent. Par’s Contentions made a passing reference to inducement, asserting conclusorily that physicians using Eagle’s ANDA product would perform the methods of the ’526 and ’209 patents and use the composition of the ’785 patent. (Ex. 2 at 2.) But Par never explained how Eagle allegedly has specific intent to cause that direct infringement. (*Id.*)

Nor did any of Par’s experts address intent in their burden of proof reports.

Instead, the first and only time Par disclosed any “specific intent” theory was in Dr. Kirsch’s *reply* report, where he opined that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] (Ex. 3 ¶¶43-46, 69-70.) Even if this were a viable theory—which Eagle disputes—“Plaintiffs should not be permitted to advance a new infringement theory in their [expert’s] reply report,” because that violates Federal Rule of Civil Procedure 26(a). *Zimmer Surgical, Inc. v. Stryker Corp.*, 365 F. Supp. 3d 466, 498, 502 (D. Del. 2019).

As “the party that failed to make the required disclosure, [Par] bears the ‘burden of proving substantial justification for its conduct or that the failure to produce was harmless.’” *W.L. Gore & Assocs., Inc. v. C.R. Bard, Inc.*, 2015 WL 12806484, at *3 n.4 (D. Del. Sept. 25, 2015) (citation omitted). In determining whether to permit untimely expert opinion, courts consider the: (1) prejudice or surprise to the opposing party; (2) likelihood of disruption of the trial; (3) possibility of curing the prejudice; (4) explanation for the failure to disclose; (5) presence of bad faith or willfulness in not disclosing the evidence; and (6) importance of the information withheld. *Zimmer*, 365 F. Supp. 3d at 498–99. Weighing these factors supports exclusion.

Eagle has been prejudiced. Because Par’s theory was not disclosed until its expert’s reply report, Eagle and its experts could not respond. Nor was Eagle able to explore Dr. Kirsch’s opinions at his deposition, as he was [REDACTED]

[REDACTED] (See, e.g., Ex. 4 at 25:7-14 [REDACTED]
[REDACTED]
[REDACTED] 29:20-30:7 [REDACTED]
[REDACTED]
[REDACTED]

Further, this prejudice cannot be cured because expert discovery is closed. And even if Par's untimely theory does not disrupt the trial, "that by itself does not overcome the prejudice" suffered by Eagle. *See Zimmer*, 365 F. Supp. 3d at 502.

Potential importance to Par's inducement case does not change that "exclusion is necessary" given Par's "flouting of discovery deadlines." *Praxair, Inc. v. ATMI, Inc.*, 231 F.R.D. 457, 436 (D. Del. 2005), *rev'd on other grounds*, 543 F.3d 1306 (Fed. Cir. 2008). Indeed, the importance of the evidence just reaffirms Eagle's prejudice.

Finally, Par has no reasonable explanation for its untimely disclosure. During fact discovery—weeks prior to opening reports—Eagle raised the lack of specific intent in its non-infringement contentions. (*E.g.*, Ex. 1 at Ex. A at 5, Ex. B at 10.) Yet Par selectively withheld its intent theory until Dr. Kirsch's reply report, despite bearing the burden on infringement. There was no reason for Par to do so other than to shield that theory from discovery.

Eagle's motion *in limine* should be granted.

Date: May 11, 2020

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Date: May 11, 2020

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EXHIBIT 1

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

PAR PHARMACEUTICAL, INC., PAR
STERILE PRODUCTS, LLC, and ENDO
PAR INNOVATION COMPANY, LLC,

Plaintiffs,

v.

EAGLE PHARMACEUTICALS INC.,

Defendant.

C.A. No. 18-823-CFC

**EAGLE’S SECOND SUPPLEMENTAL OBJECTIONS AND RESPONSES TO
PLAINTIFFS’ INTERROGATORY NOS. 1, 8, AND 9**

Pursuant to Federal Rules of Civil Procedure 26 and 33, Defendant Eagle Pharmaceuticals Inc. (“Eagle”) hereby provides second supplemental responses to Plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC’s (collectively, “Par’s”) First Set of Interrogatories to Eagle Pharmaceuticals Inc. (“Interrogatories” and each individually, an “Interrogatory”) as set forth below.

No incidental or implied admissions are intended by the responses provided herein. The fact that Eagle has provided a response to any particular Interrogatory should not be taken as an admission that Eagle accepts or admits the existence of any fact, interpretation, or conclusion of law set forth or assumed by such Interrogatory or that such response constitutes admissible evidence. The fact that Eagle has provided a response to any Interrogatory is not intended to be, and shall not be construed as, a waiver by Eagle of any part of any objection to any such Interrogatory.

GENERAL RESPONSES AND OBJECTIONS

Eagle hereby incorporates by reference and restates the General Responses and Objections set forth in Eagle's Objections and Responses to Par's First Set of Interrogatories to Eagle, served on September 27, 2018.

INTERROGATORIES

INTERROGATORY NO. 1:

Describe in detail the complete basis for any contention by you that the Eagle ANDA and your proposed commercial manufacture and sale of the Eagle Vasopressin Injection Products have not infringed and will not infringe any asserted claim of the patents-in-suit, including without limitation the bases for your "Second Defense," "Third Defense," "First Counterclaim," "Third Counterclaim," "Fifth Counterclaim," "Seventh Counterclaim," "Ninth Counterclaim," and "Eleventh Counterclaim," in Eagle's Answer to Complaint & Counterclaims (D.I. 9).

The detailed description should include, on a claim-by-claim basis, the identity of each claim limitation you contend is not met, either literally or under the doctrine of equivalents; the identity of all facts on which you base each such contention; the identity of each person with knowledge of those facts and the knowledge you believe each such person has; and the identity of each document on which you base each such contention.

RESPONSE TO INTERROGATORY NO. 1:

Eagle incorporates by reference the above-stated General Responses and Objections as if fully set forth herein. Eagle objects to this Interrogatory to the extent it contains multiple subparts asserted as a single interrogatory. Eagle also objects to this Interrogatory to the extent it calls for a legal conclusion. Eagle further objects to the phrases "the complete basis for any contention by you that the Eagle ANDA and your proposed commercial manufacture and sale of the Eagle

Vasopressin Injection Products have not infringed and will not infringe any asserted claim of the patents-in-suit,” “the identity of all facts on which you base each such contention,” “the identity of each person with knowledge of those facts,” and “the identity of each document on which you base each such contention” as overbroad, vague, and ambiguous including because they are of unclear scope and are undefined in Par’s Definitions and Instructions. Eagle further objects to this Interrogatory as premature to the extent it seeks information that will be the subject of expert opinion and testimony at this early stage of this proceeding and before the Scheduling Order is entered in this matter. Eagle further objects to this Interrogatory to the extent it seeks Eagle’s contentions prior to Par’s identification of asserted claims and service of an “initial claim chart relating each known accused product to the asserted claims each such product allegedly infringes,” as provided in the parties’ proposed Scheduling Order, submitted to the Court on September 5, 2018. Eagle further objects to this Interrogatory to the extent it attempts to improperly shift the burden regarding patent infringement, on which Par bears the burden of proof. The parties’ proposed Scheduling Order, for example, expressly provides that “contention interrogatories, if filed, shall first be addressed by the party with the burden of proof,” requiring Par to provide its infringement contentions prior to any noninfringement contentions by Eagle. Eagle further objects to this Interrogatory to the extent it seeks information protected by privilege and/or the work product doctrine.

Subject to and without waiving its Specific and General Objections, Eagle responds as follows:

Eagle incorporates by reference the bases for Eagle’s non-infringement of each of the patents-in-suit as set forth in its notices to Par, dated April 16, 2018 and May 18, 2018, that ANDA No. 211538 included Paragraph IV certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the

patents-in-suit are invalid, unenforceable, and/or will not be infringed by Eagle's Proposed ANDA. Eagle additionally incorporates by reference any expert reports to be submitted by Eagle in this case that provide bases for Eagle's non-infringement contentions, which will be served in accordance with the Scheduling Order. Eagle will provide additional responses in due course, pursuant to the Scheduling Order (when entered) and following service of Par's disclosure of asserted claims and infringement contentions. Discovery is ongoing and Eagle reserves the right to supplement Eagle's responses as discovery progresses.

FIRST SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 1:

Subject to and without waiving its Specific and General Objections, Eagle responds as follows:

Eagle incorporates by reference the bases for Eagle's non-infringement of each of the patents-in-suit as set forth in Exhibits A–F attached hereto. Discovery is ongoing and Eagle reserves the right to supplement Eagle's responses as discovery progresses.

SECOND SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 1:

Subject to and without waiving its Specific and General Objections, Eagle responds as follows:

Eagle incorporates by reference additional bases for Eagle's non-infringement of the '526, '209, and '785 patents as set forth in Exhibits A–C attached hereto. Eagle reserves the right to supplement or amend Eagle's responses based on any discovery produced after the October 28, 2019 deadline set in the Scheduling Order. *See* D.I. 117.

INTERROGATORY NO. 8:

Identify and describe in detail the status of the Eagle ANDA.

therein): EAGLEVAS0043552–0051562. Eagle reserves the right to supplement or amend Eagle’s responses based on any discovery produced after the October 28, 2019 deadline set in the Scheduling Order. *See* D.I. 117.

Date: October 28, 2019

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Exhibit A

Eagle's First Supplemental Non-Infringement Claim Chart - US Patent No. 9,687,526

Claim	Non-Infringement Contention(s) ¹
1[a]. A method of increasing blood pressure in a human in need thereof, the method comprising:	<p>As set forth in Eagle's Final Invalidity Contentions, this claim is invalid. Because it is axiomatic that invalid patent claims cannot be infringed, Eagle cannot infringe this claim.</p> <p>Eagle does not, and will not, administer any product or otherwise directly practice the claimed method. As such, Eagle will not itself practice any method of "increasing blood pressure in a human in need thereof," including the claimed method.</p> <p>Plaintiffs' Final Infringement Contentions and Exhibit A Infringement Claim Chart For U.S. Patent No. 9,687,526 ("Par's Final '526 Infringement Contentions") do not clearly provide the identity of an alleged direct infringer who would allegedly practice every element of this method claim. Furthermore, Par has provided no evidence that a single infringer would perform all of the required steps. <i>Limelight Networks, Inc. v. Akamai Techs., Inc.</i>, 572 U.S. 915, 923 (2014) ("in this case, performance of all the claimed</p>

¹ Plaintiffs bear the burden of proving that Eagle's ANDA Product infringes the Asserted Claims. Eagle does not concede that Plaintiffs have met their burden of proving that Eagle's ANDA Product, or use thereof, will meet any element of the Asserted Claims, and Eagle reserves the right to challenge the sufficiency of Plaintiffs' proof with respect to any and all elements of the Asserted Claims. Eagle also reserves the right to supplement, amend, and/or modify its affirmative non-infringement contentions with respect to the Asserted Claims based on documents produced or disclosed in this action, including any documents cited in Plaintiffs' expert reports in this case. Eagle further reserves the right to supplement, amend, and/or modify its affirmative non-infringement contentions with respect to the Asserted Claims in response to any argument raised in Plaintiffs' expert reports to be served in accordance with the Amended Scheduling Order. D.I. 92.

Moreover, Eagle's ANDA Product [REDACTED] To the extent Plaintiffs contend that Eagle's ANDA Product infringes the Asserted Claims, the prior art necessarily anticipates, or at least renders obvious, the Asserted Claims.

Eagle also incorporates by reference its Final Invalidity Contentions explaining why the Asserted Claims are, in any event, invalid. Invalid claims cannot be infringed. Accordingly, Eagle's ANDA Product, and the proposed manufacture, sale, offer for sale, and use of Eagle's ANDA Product, cannot infringe the Asserted Claims.

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Claim	Non-Infringement Contention(s) ¹
	<p>steps cannot be attributed to a single person, so direct infringement never occurred”). Therefore, Par has failed to carry its burden for establishing infringement.</p> <p>Further, as explained in Eagle’s Final Invalidity Contentions, Eagle’s ANDA Product is, in all material respects with regard to the elements of this claim. [REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p><i>E.g.</i>, EAGLEVAS0043675; PAR-VASO_0072474. Par has admitted that the claims of this patent do not encompass original Vasostrict®. Sept. 6, 2019 Email from S. Gagliardi to C. Citro. [REDACTED]</p>
1[b]. a) providing a pharmaceutical composition for intravenous administration comprising:	Eagle will not “provid[e] a pharmaceutical composition for intravenous administration” with the claimed properties.

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Claim	Non-Infringement Contention(s) ¹
1[c]. i) from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically-acceptable salt thereof;	See 1[a].
1[d]. ii) acetic acid; and iii) water,	See 1[a].
1[e]. wherein the pharmaceutical composition has a pH of 3.8;	<div data-bbox="716 508 1864 841" style="background-color: black; width: 100%; height: 205px;"></div> <p data-bbox="716 841 1864 1133">Nor could Par capture Eagle's ANDA Product under the doctrine of equivalents, given that the applicants relied on the claimed pH range as "critical[]" in order to overcome prior art. Office Action Response (Appl. No. 15/289,640 ('526 patent)) (May 2, 2017) at 7–11; <i>see Pharmacia & Upjohn Co. v. Mylan Pharm., Inc.</i>, 170 F.3d 1373, 1377–78 (Fed. Cir. 1999) (precluding patentee from relying on the doctrine of equivalents to capture compositions without spray-dried lactose because the patentee described spray-dried lactose as "a critical feature" of the invention).</p> <p data-bbox="716 1166 1864 1239">In support of its contention that Eagle's ANDA product "can be expected to reach a pH of at least 3.8 within the requested shelf-life," Par's Final '526 Infringement</p> <div data-bbox="716 1239 1864 1421" style="background-color: black; width: 100%; height: 112px;"></div>

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Claim	Non-Infringement Contention(s) ¹
	<div data-bbox="716 261 1850 878" style="background-color: black; width: 100%; height: 380px;"></div> <p data-bbox="716 878 1850 959">Thus, based on the inventors' testimony, the pH value recited in this claim appear to refer only to the initial pH, and not to a pH measured after storage.</p> <div data-bbox="716 959 1835 1057" style="background-color: black; width: 100%; height: 60px;"></div> <p data-bbox="716 1057 1850 1097"><i>See, e.g.,</i> EAGLEVAS00047274.</p> <div data-bbox="716 1122 1850 1284" style="background-color: black; width: 100%; height: 100px;"></div> <p data-bbox="716 1300 1850 1421">Par has asserted in its infringement contentions that "Eagle's ANDA product will satisfy this limitation during the time of its intended use." Par's Final '526 Infringement Contentions at 2. Par's unsupported speculation cannot satisfy Par's</p>

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Claim	Non-Infringement Contention(s) ¹
	<p>burden of demonstrating that Eagle’s ANDA Product will infringe. Moreover, even if Par’s speculation were true, Par has not provided any evidence that the recited pH limitation would be met when Eagle’s ANDA Product is made, sold or used. Nor can Par demonstrate the requisite specific intent for induced infringement. [REDACTED]</p> <p>[REDACTED]</p> <p>Similarly, there is no contributory infringement because the use for which Eagle’s ANDA Product would be approved would <i>not meet</i> this claimed pH. The use for which Eagle’s ANDA Product would be FDA-approved, <i>i.e.</i>, [REDACTED] is a substantial non-infringing use that precludes the finding of contributory infringement.</p>
<p>1[f]. b) storing the pharmaceutical composition at 2-8° C for at least 4 weeks; and</p>	<p>Eagle’s proposed prescribing information does not encourage third parties, including patients or physicians, to perform this claim step because Eagle’s proposed prescribing information [REDACTED] <i>see also</i> EAGLEVAS0000306 at 308; EAGLEVAS0000429 at 437. Accordingly, Eagle lacks the specific intent to cause infringement of this claim for at least the reason that Eagle’s ANDA and proposed prescribing information does not provide an instruction on whether the pharmaceutical composition must be stored “for at least 4 weeks.”</p>
<p>1[g]. c) intravenously administering the pharmaceutical composition to the human,</p>	<p>Eagle will not “itself intravenously administer[] [a] pharmaceutical composition to [a] human.”</p>

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Claim	Non-Infringement Contention(s) ¹
	Furthermore, for the reasons discussed above, Eagle will not encourage any third party, including a physician or patient, to “administer[] <i>the</i> pharmaceutical composition” recited in the claims. <i>See</i> 1[b] and 1[e] (emphasis added).
1[h]. wherein the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute,	Eagle will not “itself intravenously administer[] [a] pharmaceutical composition to [a] human.” Furthermore, for the reasons discussed above, Eagle will not encourage any third party, including a physician or patient, to “administer[] <i>the</i> pharmaceutical composition” recited in the claims. <i>See</i> 1[b] and 1[e] (emphasis added).
1[i]. wherein the human is hypotensive,	Eagle will not itself practice any method of “increasing blood pressure in a human in need thereof,” including the claimed method, including on any human who is “hypotensive.” <i>See</i> 1[a].
1[j]. wherein the pharmaceutical composition exhibits less than about 5% degradation after storage at 2-8° C for about four weeks.	Eagle’s proposed prescribing information does not encourage third parties, including patients or physicians, to perform this claim step because Eagle’s proposed prescribing information [REDACTED] [REDACTED] Accordingly, Eagle lacks the specific intent to cause infringement of this claim for at least the reason that Eagle’s ANDA and proposed prescribing information does not provide an instruction on whether the pharmaceutical composition must be stored “for at least 4 weeks.” Eagle also will not encourage third parties, including patients or physicians, to provide for intravenous administration of a pharmaceutical composition comprising “less than about 5% degradation.” As an initial matter, Par’s Final ’526 Infringement Contentions do not clearly define the scope of the claim element at issue (<i>e.g.</i> , what this claim means and what the percent of

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Claim	Non-Infringement Contention(s) ¹
	<p>degradation is measured relative to). For example, Par has not made clear whether the relevant numerator for calculating the percentage limitation recited in the phrase “less than about 5% degradation” refers to the amount of vasopressin lost, amount of degradation products formed, or some other amount. Indeed, Par’s Final ’526 Infringement Contentions cite to both assay vasopressin acceptance criteria (label claim for vasopressin assay) and the percent degradation products formed as evidence that Eagle’s ANDA Product purportedly meets this claim limitation. Par’s Final ’526 Infringement Contentions at 4. Nor has Par made clear what the relevant denominator is, for example, whether it refers to the initial amount of vasopressin, the amount of vasopressin at the time of measurement, or some other amount. Par has provided no indication as to, inter alia, whether its theory of infringement rests on relative or absolute changes in either the vasopressin assay or the degradation products. Having failed to clarify what would and what would not infringe this claim, Par has failed to carry its burden of establishing infringement.</p> <p>To the extent this claim limitation not indefinite, Par has not shown that Eagle’s ANDA Product as “provid[ed]” will meet this limitation. For example, the Specification for Release and the Specification for Stability in Eagle’s ANDA provide the limits of [REDACTED] EAGLEVAS0046173; <i>see also</i> EAGLEVAS00001328 at 1328–29. Further, the Specification for Release and the Specification for Stability in Eagle’s ANDA each provide a limit of [REDACTED] EAGLEVAS046173; <i>see also</i> EAGLEVAS00001328. Because Eagle will not specifically encourage use of a pharmaceutical composition with “less than about 5% degradation” within the broader limits set forth in Eagle’s ANDA, Eagle lacks the specific intent to cause infringement of this claim.</p>
2[a]. The method of claim 1,	Eagle will not perform “[t]he method of claim 1,” nor will it encourage any third party, including a physician or patient, to perform “[t]he method of claim 1.” <i>See</i> claim 1.
2[b]. wherein the pharmaceutical composition further comprises SEQ	Par has not met its burden of showing that Eagle’s ANDA Product will “include SEQ ID No.: 2” when “provid[ed],” much less at the claimed level. Par also has not shown

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Exhibit B

Eagle's First Supplemental Non-Infringement Claim Chart - US Patent No. 9,744,209

Claim	Non-Infringement Contention(s) ¹
1[a]. A method of increasing blood pressure in a human in need thereof, the method comprising administering to the human a unit dosage form, wherein	<p>As set forth in Eagle's Final Invalidity Contentions, this claim is invalid. Because it is axiomatic that invalid patent claims cannot be infringed, Eagle cannot infringe this claim.</p> <p>Eagle does not, and will not, administer any product or otherwise directly practice the claimed method. As such, Eagle will not itself practice any method of "increasing blood pressure in a human in need thereof," nor "administering to the human a unit dosage form," including the claimed method.</p> <p>Plaintiffs' Final Infringement Contentions and Exhibit B Infringement Claim Chart For U.S. Patent No. 9,744,209 ("Par's Final '209 Infringement Contentions") do not clearly provide the identity of an alleged direct infringer who would allegedly practice</p>

¹ Plaintiffs bear the burden of proving that Eagle's ANDA Product infringes the Asserted Claims. Eagle does not concede that Plaintiffs have met their burden of proving that Eagle's ANDA Product, or use thereof, will meet any element of the Asserted Claims, and Eagle reserves the right to challenge the sufficiency of Plaintiffs' proof with respect to any and all elements of the Asserted Claims. Eagle also reserves the right to supplement, amend, and/or modify its affirmative non-infringement contentions with respect to the Asserted Claims based on documents produced or disclosed in this action, including any documents cited in Plaintiffs' expert reports in this case. Eagle further reserves the right to supplement, amend, and/or modify its affirmative non-infringement contentions with respect to the Asserted Claims in response to any argument raised in Plaintiffs' expert reports to be served in accordance with the Amended Scheduling Order. D.I. 92.

Moreover, Eagle's ANDA Product [REDACTED] To the extent Plaintiffs contend that Eagle's ANDA Product infringes the Asserted Claims, the prior art necessarily anticipates, or at least renders obvious, the Asserted Claims.

Eagle also incorporates by reference its Final Invalidity Contentions explaining why the Asserted Claims are, in any event, invalid. Invalid claims cannot be infringed. Accordingly, Eagle's ANDA Product, and the proposed manufacture, sale, offer for sale, and use of Eagle's ANDA Product, cannot infringe the Asserted Claims.

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Claim	Non-Infringement Contention(s) ¹
	<p>every element of this method claim. Furthermore, Par has provided no evidence that a single infringer would perform all of the required steps. <i>Limelight Networks, Inc. v. Akamai Techs., Inc.</i>, 572 U.S. 915, 923 (2014) (“in this case, performance of all the claimed steps cannot be attributed to a single person, so direct infringement never occurred”). Therefore, Par has failed to carry its burden for establishing infringement.</p> <p>Further, as explained in Eagle’s Final Invalidity Contentions, [REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p><i>E.g.</i>, EAGLEVAS0043675; PAR-VASO_0072474. Par has admitted that the claims of this patent do not encompass original Vasostrict®. Sept. 6, 2019 Email from S. Gagliardi to C. Citro. [REDACTED]</p> <p>[REDACTED]</p>

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Claim	Non-Infringement Contention(s) ¹
1[b]. the unit dosage form comprises from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically acceptable salt thereof, wherein:	<i>See 1[a].</i>
1[c]. the unit dosage form has a pH of 3.7-3.9;	<p>Eagle's ANDA does not encourage third parties, including patients or physicians, to perform this claim step requiring administration of a unit dosage form which "has a pH of 3.7-3.9." Eagle's ANDA product does not have a pH of 3.7-3.9. [REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED] A [REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>Nor could Par capture Eagle's ANDA Product under the doctrine of equivalents, given that the applicants relied on the claimed pH range as "critical[]" in order to overcome prior art. Office Action Response (Appl. No. 15/426,693 ('209 patent)) (June 28, 2017) at 8; <i>see Pharmacia & Upjohn Co. v. Mylan Pharm., Inc.</i>, 170 F.3d 1373, 1377-78 (Fed. Cir. 1999) (precluding patentee from relying on the doctrine of equivalents to capture compositions without spray-dried lactose because the patentee described spray-dried lactose as "a critical feature" of the invention).</p> <p>In support of its contention that Eagle's ANDA product "can be expected to reach a pH of at least 3.7 or 3.8 within the requested shelf-life," Par's Final '209 Infringement [REDACTED]</p>

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Claim	Non-Infringement Contention(s) ¹
	<p>[REDACTED]</p> <p>First, the inventors of the patents-in-suit each testified that initial or target pH values are used to compare formulations, including for the data submitted in support of the purported criticality of this pH limitation. Kannan Dep. 168:19–172:2; Vandse Dep. 93:11–100:4; Kenney Dep. 257:10–25; Sanghvi Dep. 135:13–23. Thus, based on the inventors’ testimony, the pH value recited in this claim appear to refer only to the initial pH and not to a pH measured after storage.</p> <p>[REDACTED]</p> <p>Thus, Eagle’s ANDA product cannot meet the initial pH limitation recited here.</p> <p>[REDACTED]</p>

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Claim	Non-Infringement Contention(s) ¹
	<p>Par has asserted in its infringement contentions that “Eagle’s ANDA product will satisfy this limitation during the time of its intended use.” Par’s Final ’209 Infringement Contentions at 2. Par’s unsupported speculation cannot satisfy Par’s burden of demonstrating that Eagle’s ANDA Product will infringe. Moreover, even if Par’s speculation were true, Par has not provided any evidence that the recited pH limitation would be met when Eagle’s ANDA Product is made, sold or used.</p> <div data-bbox="705 496 1845 829" style="background-color: black; height: 205px; width: 100%;"></div> <p>Similarly, there is no contributory infringement because the use for which Eagle’s ANDA Product would be approved would fall <i>outside</i> this claimed pH range. The use for which Eagle’s ANDA Product would be FDA-approved, <i>i.e.</i>, [REDACTED] is a substantial non-infringing use that precludes the finding of contributory infringement.</p>
<p>1[d]. the unit dosage form further comprises impurities that are present in an amount of 0.9% - 1.7%,</p>	<p>Eagle will not encourage third parties, including patients or physicians, to perform this claim limitation, which requires administering a unit dosage form which “further comprises impurities that are present in an amount of 0.9% - 1.7%.” [REDACTED]</p> <div data-bbox="705 1166 1845 1271" style="background-color: black; height: 65px; width: 100%;"></div> <p>[REDACTED] Par has not shown that Eagle’s ANDA Product will meet this limitation. Furthermore, because Eagle will not specifically encourage use of a unit dosage form with “impurities that are present in an amount of 0.9% -</p>

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Claim	Non-Infringement Contention(s) ¹
	<p>1.7%” within the broader limits set forth in Eagle’s ANDA, Eagle lacks the specific intent to cause infringement of this claim.</p> <p>Par also has not shown that Eagle’s ANDA Product will meet this limitation based on its assertion that “[s]tability data submitted on Eagle’s ANDA product demonstrates the presence of various impurities that have 85-100% sequence homology to SEQ ID No. 1.” Par’s Final ’209 Infringement Contentions at 2. Although Par identified a number of particular impurities, it did not disclose how it calculated sequence homology. There are numerous methods for calculating sequence homology that lead to different results for the same peptides. <i>See, e.g., Butamax™ Advanced Biofuels LLC v. Gevo, Inc.</i>, 117 F. Supp. 3d 632, 639 (D. Del. 2015). During his deposition, Matthew Kenney [REDACTED]</p> <p>12, 252:6–14, 255:23–256:9. Without setting forth how to determine whether a particular impurity has the requisite sequence homology to count towards this numerical limitation, Par cannot demonstrate that Eagle’s ANDA product ever meets this limitation.</p> <p>Additionally, the results cited by Par for Eagle’s ANDA product include unidentified impurities. Par has provided no evidence that these impurities meet or do not meet the sequence homology requirement of this limitation and count towards the percent impurity limitation. Par thus cannot establish that the numerical impurity requirements of this claim are ever satisfied by Eagle’s ANDA product.</p> <p>Par’s Final ’209 Infringement Contentions do not clearly define the scope of the claim element at issue (<i>e.g.</i>, what this claim means and what the percent impurities is measured relative to). As such, Par has failed to carry its burden of establishing infringement. Indeed, Par’s infringement theory inappropriately relies on raw percent impurities values. Par, however, has not and cannot establish that percent impurities as recited in this claim refers to the same calculated values in Eagle’s ANDA. Indeed, Michelle Rennwald [REDACTED] <i>See, e.g., Rennwald</i></p>

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Claim	Non-Infringement Contention(s) ¹
	<p>Dep. 133:23–145:24, 146:1–21, 152:24–157:24. Mathew Kenney and Brian Boesch also provided similar testimony. See, e.g., Kenney Dep. 143:17–24; Boesch Dep. 198:10–25, 201:8–203:23. Therefore, Par’s bare citation of percent impurities values from Eagle’s ANDA recorded and calculated using Eagle’s method cannot establish whether Eagle’s ANDA product meets the specific impurities limitation according to this particular claim and patent.</p> <p>Moreover, Matthew Kenney [REDACTED] See, e.g., Kenney Dep. 141:5–144:22. [REDACTED] Therefore, Par cannot prove that Eagle’s ANDA product meets this impurity limitation based on testing using different equipment, by different analysts, and at different locations.</p> <p>Furthermore, contrary to Par’s assertion that “[t]he stability data generated thus far for Eagle’s proposed products confirms infringement of this limitation,” Par has not presented evidence suggesting that any product marketed by Eagle, much less used in the claimed method, would meet this claimed limitation. [REDACTED] data in Eagle’s ANDA shows that the amount of specified or unspecified degradation [REDACTED]</p> <div style="text-align: right;"><p>Par has not provided any</p></div>

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Claim	Non-Infringement Contention(s) ¹
	<p>evidence demonstrating that Eagle’s ANDA Product will meet this limitation when made, sold or used.</p> <div data-bbox="705 362 1850 480" style="background-color: black; height: 73px; width: 100%;"></div> <p>The duration of storage, and the temperature at which the product is stored, can have substantial impact on the amount of impurities, and Par has not shown that Eagle’s ANDA Product will be stored in such a way that the total amount of specified or unspecified degradation products will fall within the claimed range of “0.9% to 1.7%” impurities. Nor has Par provided evidence that Eagle’s ANDA Product will be used at a time when the percentage of impurities is within the claimed range of “0.9% to 1.7%.”</p> <p>Because the Release and Stability specifications for Eagle’s ANDA Product permit greater than 1.7% “impurities,” the cited stability data shows Eagle’s ANDA Product will have greater than 1.7% “impurities” during its shelf life, and Eagle will not encourage administration of its ANDA Product with “impurities that are present in an amount of 0.9% - 1.7%,” Eagle lacks the specific intent to encourage third parties, including physicians or patients, to administer Eagle’s ANDA Product meeting this claim element, and will not induce infringement.</p> <p>As to alleged contributory infringement, Eagle’s ANDA Product has a substantial non-infringing use at least because it may be administered with greater than, or less than, “0.9% - 1.7%” impurities.</p>
<p>1[e]. wherein the impurities have from about 85% to about 100% sequence homology to SEQ ID NO.: 1;</p>	<p>Par has not shown that Eagle’s ANDA Product will meet this limitation for the same reasons discussed above with respect to element 1[d].</p> <p>Furthermore, Par has not shown that “[s]tability data submitted on Eagle’s ANDA product demonstrates the presence of various impurities that have 85-100% sequence homology to SEQ ID No. 1.” Par’s Final ’209 Infringement Contentions at 2.</p>

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Claim	Non-Infringement Contention(s) ¹
	<p>Although Par identified a number of particular impurities, it did not disclose how it calculated sequence homology. There are numerous methods for calculating sequence homology that lead to different results for the same peptides. <i>See, e.g., ButamaxTM Advanced Biofuels LLC v. Gevo, Inc.</i>, 117 F. Supp. 3d 632, 639 (D. Del. 2015).</p> <p>[REDACTED] <i>See, e.g., Kenney</i> Dep. 247:21–12, 252:6–14, 255:23–256:9. Without setting forth how to determine whether a particular impurity has the requisite sequence homology to count towards this numerical limitation, Par cannot demonstrate that Eagle’s ANDA product ever meets this limitation.</p> <p>Additionally, the results cited by Par for Eagle’s ANDA product include unidentified impurities. Par has provided no evidence that these impurities meet or do not meet the sequence homology requirement of this limitation and count towards the percent impurity limitation. Par thus cannot establish that the numerical impurity requirements of this claim are ever satisfied by Eagle’s ANDA product.</p>
<p>1[f]. the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute; and</p>	<p>Eagle will not itself “administer[] to [a] human a unit dosage form.”</p> <p>Furthermore, for the reasons discussed above, Eagle will not encourage any third party, including a physician or patient, to “administer[] to a human ... <i>the</i> unit dosage form” recited in the claims. <i>See</i> 1[c] and 1[e].</p>
<p>1[g]. the human is hypotensive.</p>	<p>Eagle will not itself practice any method of “increasing blood pressure in a human in need thereof,” including the claimed method, including on any human who is “hypotensive.” <i>See</i> 1[a].</p>

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Exhibit C

Eagle's First Supplemental Non-Infringement Claim Chart - US Patent No. 9,750,785

Claim	Non-Infringement Contention(s) ¹
1[a]. A pharmaceutical composition comprising, in a unit dosage form,	As set forth in Eagle's Final Invalidity Contentions, this claim is invalid. Because it is axiomatic that invalid patent claims cannot be infringed, Eagle cannot infringe this claim. Further, as explained in Eagle's Invalidity Contentions, [REDACTED] [REDACTED]

¹ Plaintiffs bear the burden of proving that Eagle's ANDA Product infringes the Asserted Claims. Eagle does not concede that Plaintiffs have met their burden of proving that Eagle's ANDA Product will meet any element of the Asserted Claims, either literally or under the doctrine of equivalents, and Eagle reserves the right to challenge the sufficiency of Plaintiffs' proof with respect to any and all elements of the Asserted Claims. Eagle also reserves the right to supplement, amend, and/or modify its affirmative non-infringement contentions with respect to the Asserted Claims based on documents produced or disclosed in this action, including any documents cited in Plaintiffs' expert reports in this case. Eagle further reserves the right to supplement, amend, and/or modify its affirmative non-infringement contentions with respect to the Asserted Claims in response to any argument raised in Plaintiffs' expert reports to be served in accordance with the Amended Scheduling Order. D.I. 92.

Moreover, Eagle's ANDA Product is [REDACTED] To the extent Plaintiffs contend that Eagle's ANDA Product infringes the Asserted Claims, the prior art necessarily anticipates, or at least renders obvious, the Asserted Claims.

Eagle also incorporates by reference its Final Invalidity Contentions explaining why the Asserted Claims are, in any event, invalid. Invalid claims cannot be infringed. Accordingly, Eagle's ANDA Product, and the proposed manufacture, sale, offer for sale, and use of Eagle's ANDA Product, cannot infringe the Asserted Claims.

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Claim	Non-Infringement Contention(s) ¹
	<div></div> <p><i>E.g.</i>, EAGLEVAS0043675; PAR-VASO_0072474. Par has admitted that the claims of this patent do not encompass original Vasostrict®. Sept. 6, 2019 Email from S. Gagliardi to C. Citro. <div></div></p>
1[b] . from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically-acceptable salt thereof,	<i>See</i> 1[a].
1[c] . wherein the unit dosage form further comprises impurities that are present in an amount of 0.9% to 1.7%,	<div></div> EAGLEVAS046173; <i>see also</i> EAGLEVAS00001328 at 1328–29. Thus, Eagle’s ANDA does not demonstrate that Eagle’s ANDA Product will meet this limitation. Par also has not shown that Eagle’s ANDA Product will meet this limitation based on its assertion that “[s]tability data submitted on Eagle’s ANDA product demonstrates the presence of various impurities that have 85-100% sequence homology to SEQ ID No. 1.” Plaintiffs’ Final Infringement Contentions and Exhibit C Infringement Claim Chart For

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Claim	Non-Infringement Contention(s) ¹
	<p>U.S. Patent No. 9,750,785 (“Par’s Final ’785 Infringement Contentions”) at 1. Although Par identified a number of particular impurities, it did not disclose how it calculated sequence homology. There are numerous methods for calculating sequence homology that lead to different results for the same peptides. <i>See, e.g., ButamaxTM Advanced Biofuels LLC v. Gevo, Inc.</i>, 117 F. Supp. 3d 632, 639 (D. Del. 2015). During his deposition, Matthew Kenney [REDACTED] <i>See, e.g., Kenney Dep. 247:21–12, 252:6–14, 255:23–256:9.</i> Without setting forth how to determine whether a particular impurity has the requisite sequence homology to count towards this numerical limitation, Par cannot demonstrate that Eagle’s ANDA product ever meets this limitation.</p> <p>Additionally, the results cited by Par for Eagle’s ANDA product include unidentified impurities. Par has provided no evidence that these impurities meet or do not meet the sequence homology requirement of this limitation and count towards the percent impurity limitation. Par thus cannot establish that the numerical impurity requirements of this claim are ever satisfied by Eagle’s ANDA product.</p> <p>Par’s Final ’785 Infringement Contentions does not clearly define the scope of the claim element at issue (<i>e.g.</i>, what this claim means and what the percent impurities is measured relative to). As such, Par has failed to carry its burden of establishing infringement. Indeed, Par’s infringement theory inappropriately relies on raw percent impurities values. Par, however, has not and cannot establish that percent impurities as recited in this claim refers to the same calculated values in Eagle’s ANDA. [REDACTED] <i>See, e.g., Rennwald Dep. 133:23–145:24, 146:1–21, 152:24–157:24. Mathew Kenney and Brian Boesch also provided similar testimony. See, e.g., Kenney Dep. 143:17–24; Boesch Dep. 198:10–25, 201:8–203:23.</i> Therefore, Par’s bare citation of percent impurities values from Eagle’s ANDA recorded and calculated using Eagle’s method cannot establish whether Eagle’s ANDA product meets the specific impurities limitation according to this particular claim and patent.</p>

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Claim	Non-Infringement Contention(s) ¹
	<p>Moreover, Matthew Kenney testified percent impurity values invariably differ based on equipment, analyst, and location. See, e.g., Kenney Dep. 141:5–144:22. Therefore, Par cannot prove that Eagle’s ANDA product meets this impurity limitation based on testing using different equipment, by different analysts, and at different locations.</p> <p>Furthermore, contrary to Par’s assertion that “[t]he stability data generated thus far for Eagle’s proposed products confirms infringement of this limitation,” Par has not presented evidence suggesting that any product marketed by Eagle would meet this claimed limitation. Id.</p> <div style="background-color: black; width: 60%; height: 180px; margin-left: 10px;"></div> <p style="margin-left: 470px;">Par has not provided any evidence demonstrating that Eagle’s ANDA Product will meet this limitation when made, sold or used.</p>
1[d]. wherein the impurities have from about 85% to about 100% sequence homology to SEQ ID NO.: 1,	<p>Par has not shown that Eagle’s ANDA Product will meet this limitation for the same reasons discussed above with respect to element 1[c].</p> <p>Furthermore, Par has not shown that “[s]tability data submitted on Eagle’s ANDA product demonstrates the presence of various impurities that have 85-100% sequence homology to SEQ ID No. 1.” Par’s Final ’785 Infringement Contentions at 1. Although Par identified a number of particular impurities, it did not disclose how it calculated sequence homology. There are numerous methods for calculating sequence homology that lead to different results for the same peptides. See, e.g., Butamax™ Advanced Biofuels LLC v. Gevo, Inc.,</p>

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Claim	Non-Infringement Contention(s) ¹
	<p>117 F. Supp. 3d 632, 639 (D. Del. 2015). [REDACTED]</p> <p>[REDACTED] See, e.g., Kenney Dep. 247:21–12, 252:6–14, 255:23–256:9. Without setting forth how to determine whether a particular impurity has the requisite sequence homology to count towards this numerical limitation, Par cannot demonstrate that Eagle’s ANDA product ever meets this limitation.</p> <p>Additionally, the results cited by Par for Eagle’s ANDA product include unidentified impurities. Par has provided no evidence that these impurities meet or do not meet the sequence homology requirement of this limitation and count towards the percent impurity limitation. Par thus cannot establish that the numerical impurity requirements of this claim are ever satisfied by Eagle’s ANDA product.</p>
1[e]. and wherein the unit dosage form has a pH of 3.7-3.9.	<p>Eagle’s ANDA Product does not have a pH of “3.7-3.9.” [REDACTED]</p> <p>[REDACTED]</p> <p>Nor could Par capture Eagle’s ANDA Product under the doctrine of equivalents, given that the applicants relied on the claimed pH range as “critical[]” in order to overcome prior art. Office Action Response (Appl. No. 15/426,703 (’785 patent)) (June 28, 2017) at 7; see <i>Pharmacia & Upjohn Co. v. Mylan Pharm., Inc.</i>, 170 F.3d 1373, 1377–78 (Fed. Cir. 1999) (precluding patentee from relying on the doctrine of equivalents to capture compositions without spray-dried lactose because the patentee described spray-dried lactose as “a critical feature” of the invention).</p> <p>In support of its contention that Eagle’s ANDA product “can be expected to reach a pH of at least 3.7 or 3.8 within the requested shelf-life,” Par’s Final ’785 Infringement</p>

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[illegible]

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Claim	Non-Infringement Contention(s) ¹
	Par has asserted in its infringement contentions that ““Eagle’s ANDA product will satisfy this limitation during the time of its intended use.” Par’s Final ’785 Infringement Contentions at 3. Par’s unsupported speculation cannot satisfy Par’s burden of demonstrating that Eagle’s ANDA Product will infringe. Moreover, even if Par’s speculation were true, Par has not provided any evidence that the recited pH limitation would be met when Eagle’s ANDA Product is made, sold or used.
2[a]. The pharmaceutical composition of claim 1,	Eagle’s ANDA Product is not a “pharmaceutical composition of claim 1,” either literally or under the doctrine of equivalents. <i>See</i> claim 1.
2[b]. wherein the impurities comprise a plurality of peptides, wherein the impurities are determined based on:	<p>Par has not shown that Eagle’s ANDA Product will meet this limitation for the same reasons discussed above with respect to elements 1[c]–[d].</p> <p>As an initial matter, Par has set forth no theory as to how the HPLC method set forth in this claim is infringed. Par appears only to identify the use of Eagle’s previous HPLC method to analyze registration batches in support of Eagle’s ANDA. Such activity is protected by the safe harbor of Title 35, Section 271(e)(1) and cannot be used to establish prior infringement by Eagle’s practice of the claimed method. In addition, Eagle’s proposed HPLC method does not meet the requirements of this claim, as set forth below. Therefore, if approved, Eagle’s ANDA product will not be analyzed by the method identified by Par.</p> <div data-bbox="758 1045 1913 1127" style="background-color: black; height: 50px; width: 100%;"></div> <p>Therefore, Par cannot prove that Eagle’s testing using different equipment, by different analysts, and at different locations meets this claim limitation.</p> <p>Furthermore, this claim injects a method step into a pharmaceutical composition claim, which renders the claim invalid as indefinite. <i>See, e.g., IPXL Holdings, LLC v. Amazon.com, Inc.</i>, 430 F.3d 1377, 1384 (Fed. Cir. 2005) (“a manufacturer or seller of the claimed apparatus would not know from the claim whether it might also be liable for contributory infringement because a buyer or user of the apparatus later performs the</p>

EXHIBIT 2

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

PAR PHARMACEUTICAL, INC., PAR
STERILE PRODUCTS, LLC, and ENDO PAR
INNOVATION COMPANY, LLC,

Plaintiffs,

v.

EAGLE PHARMACEUTICALS INC.,

Defendant.

C.A. No. 18-823 (CFC)

PLAINTIFFS' FINAL INFRINGEMENT CONTENTIONS

Pursuant to Paragraph 3(a)(vi) of the Court's Scheduling Order (D.I. 20), plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC (collectively "Par") submit the following as their disclosure of their final infringement contentions, setting forth their charts relating the accused product to the asserted claims of U.S. Patent Nos. 9,687,526 ("the '526 patent"), 9,744,209 ("the '209 patent"), and 9,750,785 ("the '785 patent") (collectively the "Patents-in-Suit").¹

I. Asserted Patents and Claims

Defendant Eagle Pharmaceuticals Inc.'s ("Eagle") submission of its ANDA to the FDA (ANDA No. 211538), including any amendments and/or supplements thereto and including the 21 U.S.C. § 355(j)(2)(A)(vii)(IV) certifications included therewith (the "Eagle ANDA"), which seeks FDA approval to engage in the commercial manufacture, use, and sale of a proposed

¹ Par hereby confirms that it is no longer asserting claims for infringement of U.S. Patent Nos. 9,375,478 and 9,937,223.

generic Vasopressin Injection USP, 20 units/1 mL (20 units/mL) product referencing Par's VASOSTRICT® products as the reference listed drug (the "Eagle ANDA Product"), constitutes infringement under 35 U.S.C. § 271(e)(2)(A) of the following claims of the Patents-in-Suit: claims 1 – 20 of the '526 patent, claims 1 – 11 and 13 of the '209 patent, and claims 1 – 9 and 11 of the '785 patent (the "Asserted Claims").

Moreover, and in addition thereto, Eagle's commercial manufacture, use, sale importation, and or offer for sale of its ANDA Product, if approved, would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the Asserted Claims of the Patents-in-Suit under 35 U.S.C. § 271(a), (b), and/or (c). For example, Eagle's commercial manufacture, use, sale, importation, and/or offer for sale of the Eagle ANDA Product would directly infringe the asserted pharmaceutical composition claims of the '785 patent. Additionally, Eagle's commercial manufacture, use, sale, importation, and/or offer for sale of the Eagle ANDA Product would also indirectly infringe the Asserted Claims of the Patents-in-Suit by inducing others to make, use, sell or offer to sell infringing products and/or inducing others to perform all of the steps of the claimed methods and use of the claimed formulations. In particular, if the Eagle ANDA Product is used and administered as intended and instructed on the proposed label for the Eagle ANDA Product, doctors, nurses and/or other medical personnel (such as, for example, the doctors, nurses, physicians' assistants, pharmacists (including clinical pharmacists) and pharmacy staff, and other medical personnel working in or with the emergency room department of a hospital), acting alone or in combination with one another, would perform each and every step of the methods of treatment recited in the Asserted Claims of the '209 and '526 patents and use the claimed formulations of the '785 patent. To the extent the steps of the claimed methods would be performed by more than one such person, the

persons performing the steps would be acting at the direction and control of the attending physician or other medical professional in charge of the treatment of the patient and/or as part of a joint enterprise (e.g., between and among the medical personnel and the hospital or other medical facility in the which the patient is being treated). Eagle has knowledge of the Patents-in-Suit, and by virtue of its proposed product label, package insert, and other conduct, Eagle would actively and intentionally induce such infringement. *See, e.g.* EAGLEVAS0000298-310; EAGLEVAS0000334-335; EAGLEVAS0043566-568; *see also AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010) (“[A] proposed label may provide evidence of [a defendant’s] affirmative intent to induce infringement” if “the proposed label instructs users to perform the patented method.”). Further, the Eagle ANDA and Eagle’s regulatory submissions demonstrate that the Eagle ANDA Product is a specifically adapted, material part of the claimed methods of treatment that has no substantial non-infringing uses.

II. Final Infringement Claim Charts

Exhibits A, B, and C attached hereto set forth Par’s final infringement claim charts for the Asserted Claims of the Patents-in-Suit, providing Par’s infringement contentions on a limitation-by-limitation basis for each of the Patents-in-Suit. Par contends the Eagle ANDA Product and performance of the claimed methods using the Eagle ANDA Product as described in the attached charts literally infringes each Asserted Claim.²

The documents and evidence identified in the charts are exemplary only, and are not an all-inclusive list of evidence in support of Eagle’s infringement of the Asserted Claims. All

² Par reserves the right to contend infringement under the doctrine of equivalents with respect to any limitation that Eagle alleges is not literally met for each Asserted Claim of the Patents-in-Suit.

references to a particular document or section of the Eagle ANDA in Par's infringement contentions include any subsequent supplements or updates to the section or document. Furthermore, citation to a specific page or pages of documents is for illustrative purpose only and does preclude reliance on additional pages from the same document.

Par notes Eagle submitted a major amendment to its ANDA on September 11, 2019. *See, e.g.*, EAGLEVAS0043614. Eagle's recently amended ANDA provides the FDA with a substantial amount of new information. Par believes that, to date, Eagle has not produced all correspondence to and from the FDA regarding Eagle's amended ANDA. Thus, any citation to an ANDA document or amendment fully incorporates by reference any subsequent amendment or supplement that has been filed or is forthcoming. Further, any citations for clarity incorporate by reference the corresponding section of Eagle's ANDA that that Eagle produced natively at EAGLEVAS0013663 and EAGLEVAS0043551.

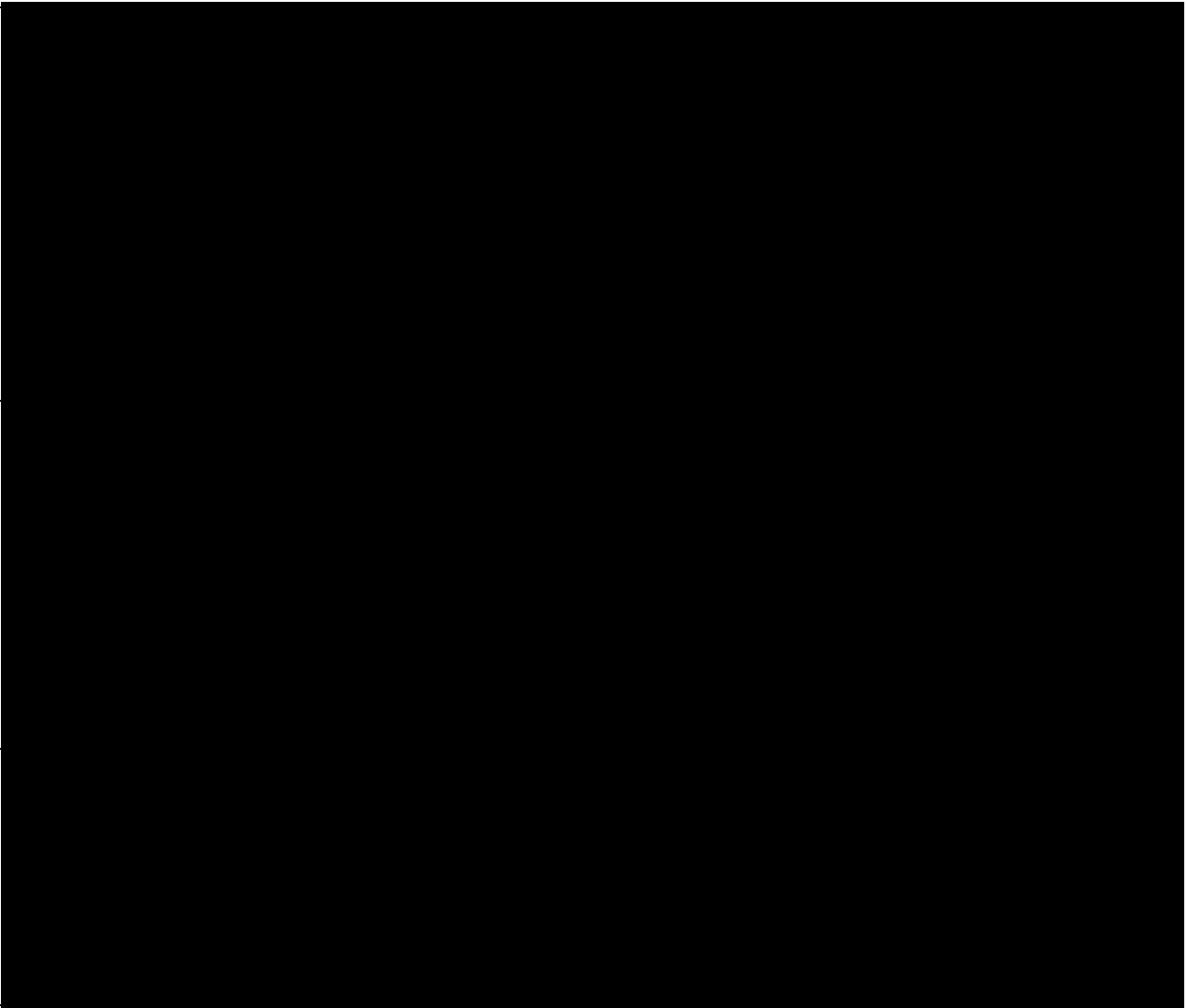
Moreover, additional deposition discovery is scheduled, including the 30(b)(6) deposition of Eagle corporate representatives.

III. Supplementation and Amendment

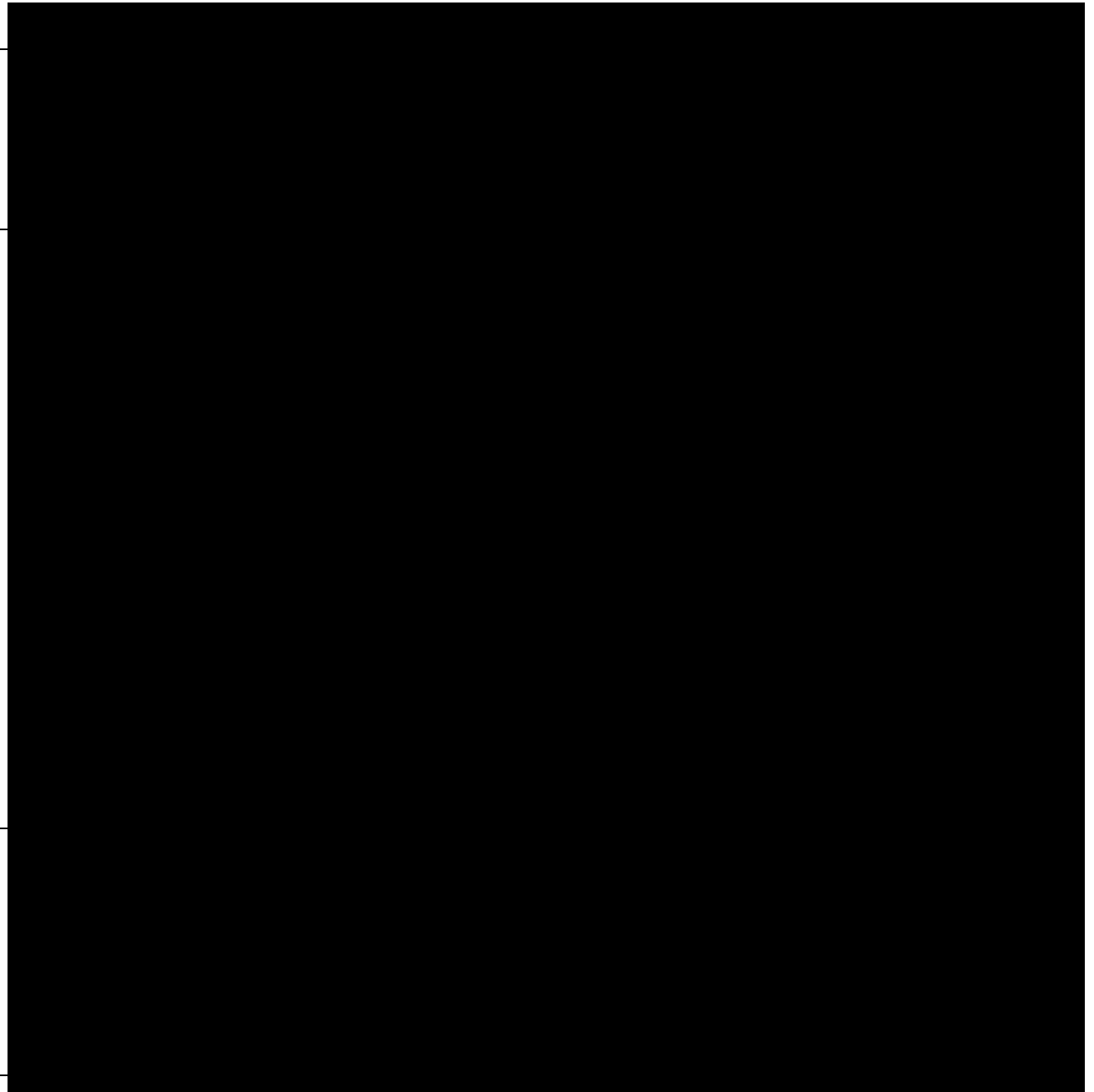
Discovery is ongoing, and Par anticipates that the subject matter of these infringement contentions will be the subject of further fact and extensive expert discovery. As noted above, this disclosure is based on the information available to Par and the discovery that they have been able to conduct as of the date of this disclosure. Par reserves the right to amend and/or supplement any of its disclosures, whether through a supplemental contention or expert report, as additional discovery is pursued, additional information is obtained from Eagle, and the investigation and analysis by any expert consultants proceed, as well as in response to any further claim construction ruling or other applicable order entered by the Court. Par reserves the

right to further modify and/or supplement these contentions with additional or different theories and/or additional or different evidence.

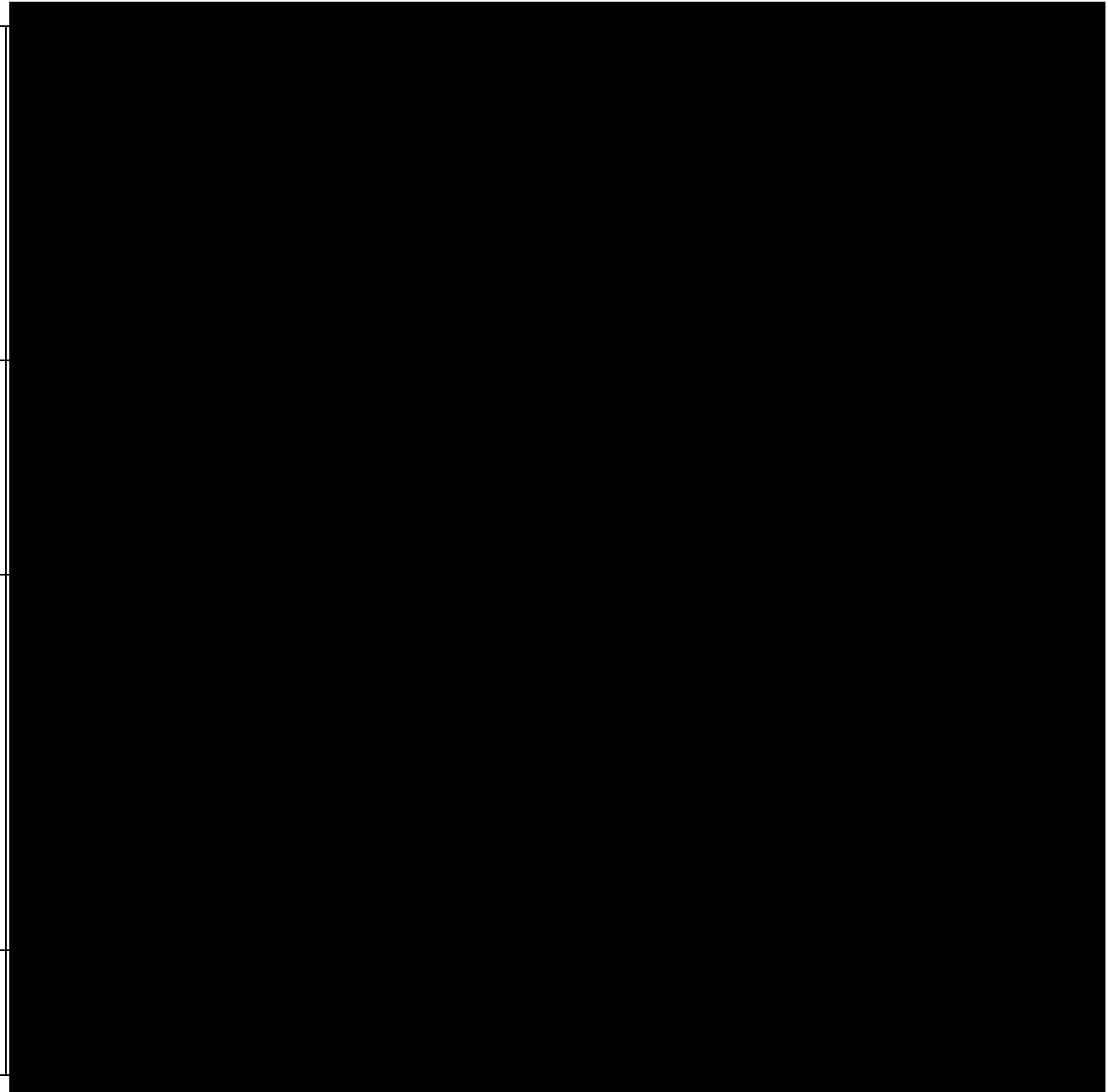
EXHIBIT A
INFRINGEMENT CLAIM CHART FOR U.S. PATENT NO. 9,687,526

1. A method of increasing blood pressure in a human in need thereof, the method comprising:	
a) providing a pharmaceutical composition for intravenous administration comprising:	
i) from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically-acceptable salt thereof;	

ii) acetic acid; and iii) water,
wherein the pharmaceutical composition has a pH of 3.8;



b) storing the pharmaceutical composition at 2-8° C for at least 4 weeks; and
c) intravenously administering the pharmaceutical composition to the human,
wherein the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt



thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute,

wherein the human is hypotensive,

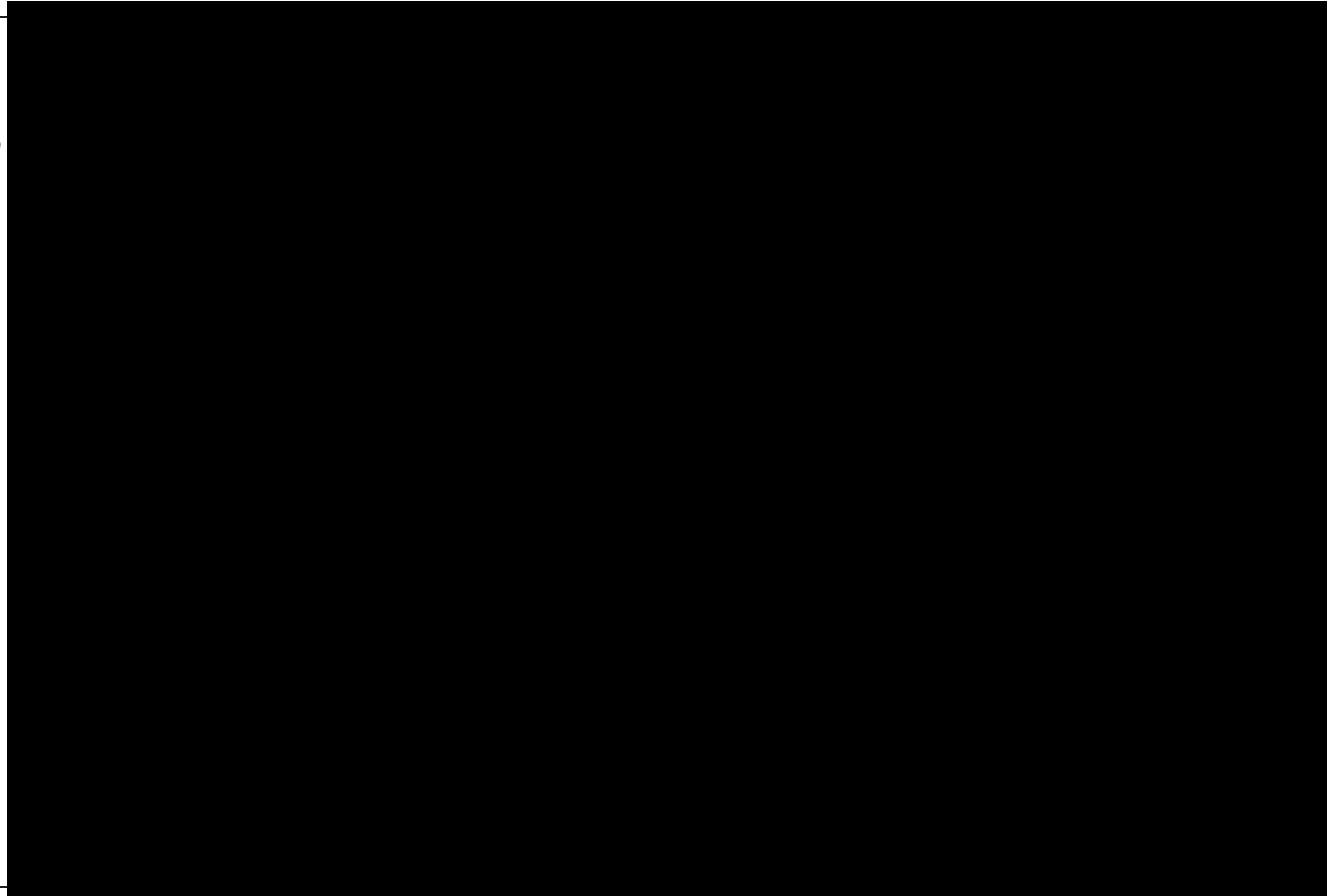
wherein the pharmaceutical composition exhibits less than about 5% degradation after storage at 2-8° C for about four weeks.

--	--

2. The method of claim 1,	See claim 1.
wherein the pharmaceutical composition further comprises SEQ ID NO: 2 in an amount of about 0.01% after storage for about 4 weeks at 2-8° C.	

EXHIBIT B
INFRINGEMENT CLAIM CHART FOR U.S. PATENT NO. 9,744,209

1. A method of increasing blood pressure in a human in need thereof, the method comprising administering to the human a unit dosage form, wherein



the unit dosage form comprises from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically acceptable salt thereof, wherein:

the unit dosage form has a pH of 3.7-3.9;

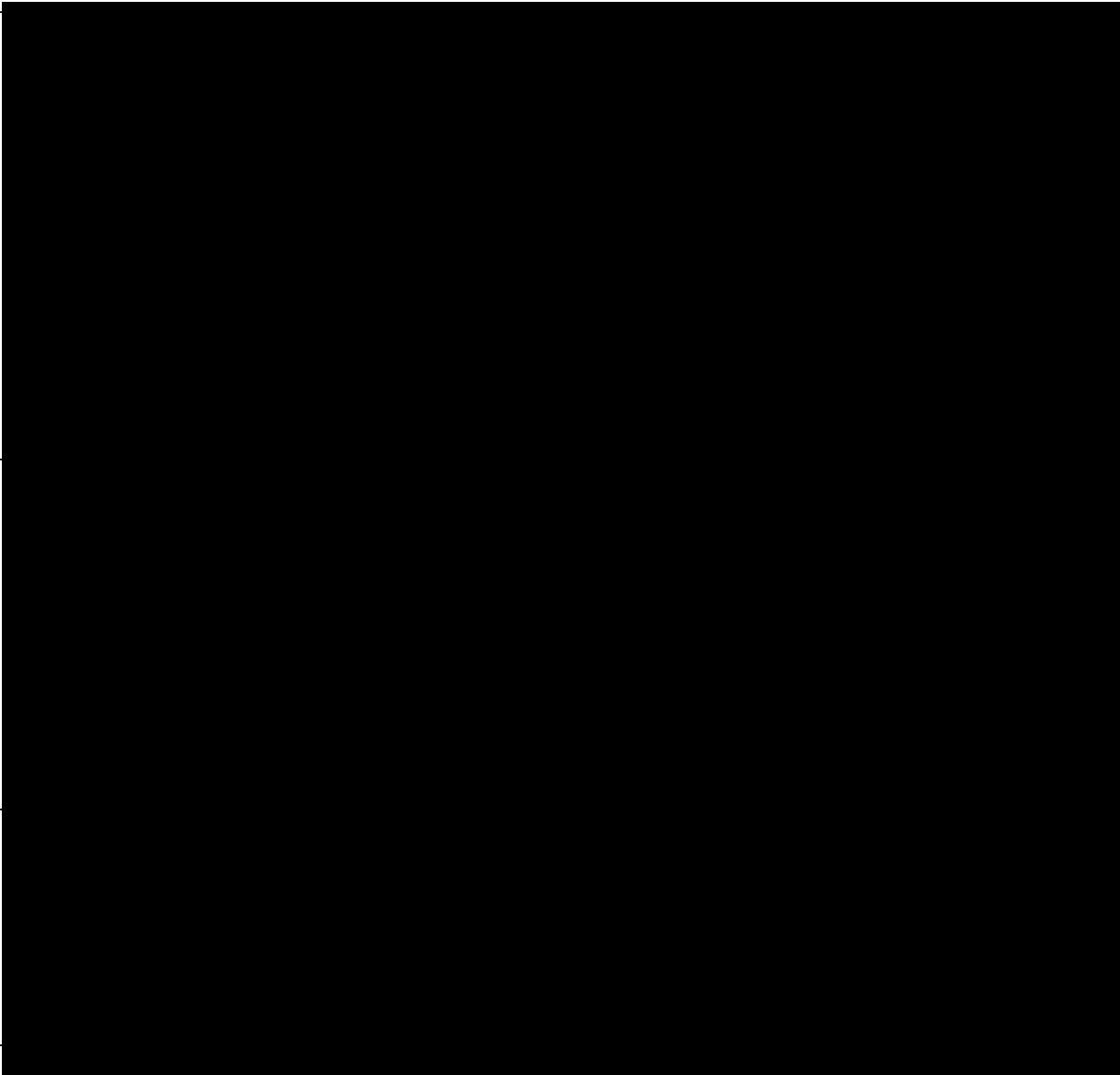
the unit dosage form further comprises impurities that are present in an amount of 0.9% - 1.7%,

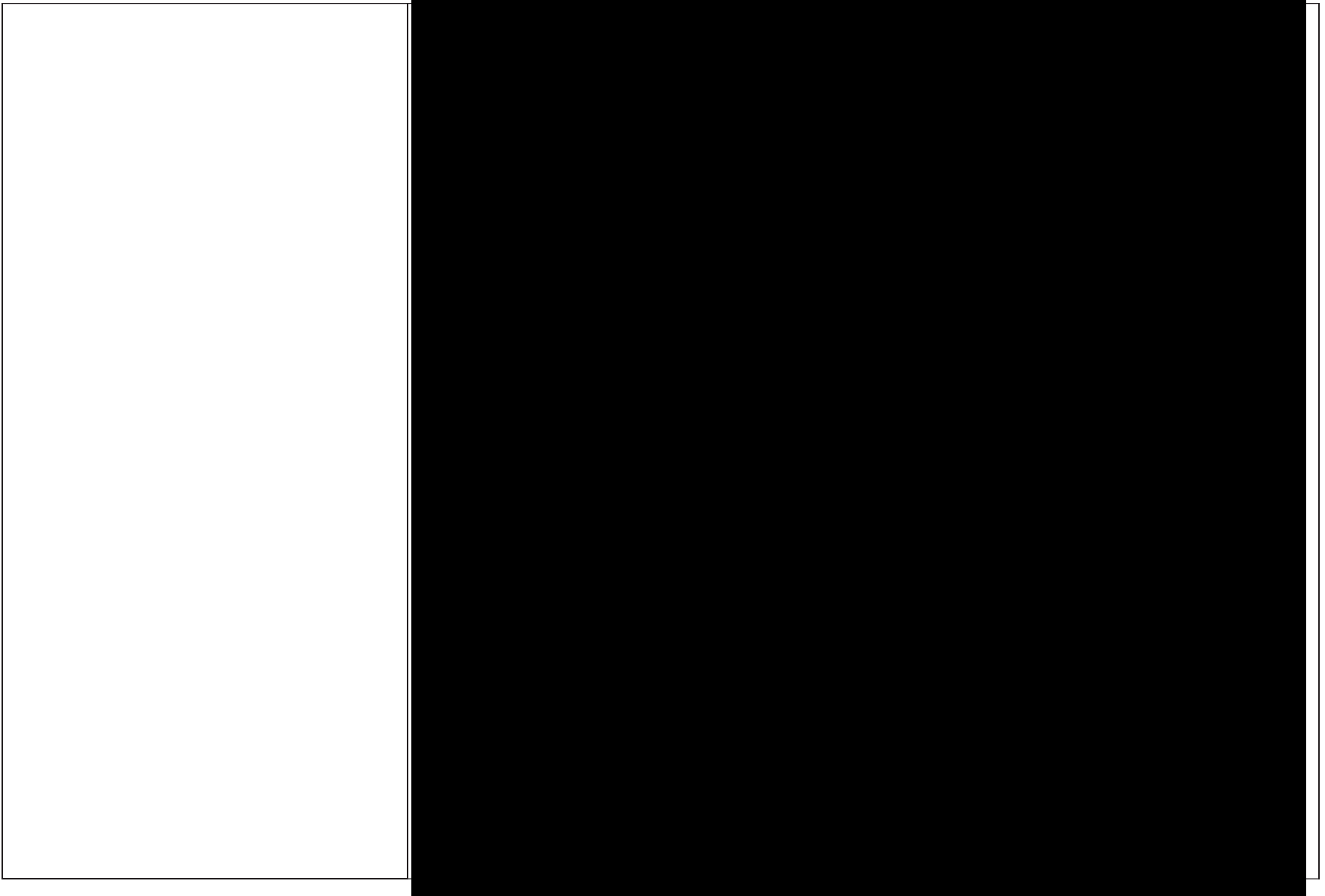
wherein the impurities have from about 85% to about	See previous limitation.

100% sequence homology to SEQ ID NO.: 1;	
the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute; and,	
the human is hypotensive.	

2. The method of claim 1,	See claim 1.
wherein the impurities comprise SEQ ID NO.: 2, and SEQ ID NO.: 2 is present in the unit dosage	

EXHIBIT C
INFRINGEMENT CLAIM CHART FOR U.S. PATENT NO. 9,750,785

1. A pharmaceutical composition comprising, in a unit dosage form,	
from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically-acceptable salt thereof,	
wherein the unit dosage form further comprises impurities that are present in an amount of 0.9% to 1.7%,	



wherein the impurities have from about 85% to about 100% sequence homology to SEQ ID NO.: 1,	See previous limitation.
and wherein the unit dosage form has a pH of 3.7-3.9.	
2. The pharmaceutical composition of claim 1,	See claim 1 above
wherein the impurities comprise a plurality of peptides, wherein the impurities are determined based on:	

EXHIBIT 3

REDACTED

EXHIBIT 4

REDACTED

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**



PAR PHARMACEUTICAL, INC.,)	
PAR STERILE PRODUCTS, LLC, and)	
ENDO PAR INNOVATION)	
COMPANY, LLC,)	
)	C.A. No. 18-823-CFC
Plaintiffs,)	
)	
v.)	
)	
EAGLE PHARMACEUTICALS INC.,)	
)	
Defendant.)	

EXHIBIT 16.2.2

**PAR'S OPPOSITION TO EAGLE'S MOTION *IN LIMINE* #2 FOR AN
ORDER PRECLUDING TESTIMONY REGARDING SPECIFIC
INTENT TO INDUCE INFRINGEMENT**

The facts supporting Par's allegations of induced infringement were properly disclosed in Par's infringement contentions and opening expert reports. In short, Par will prove Eagle seeks FDA-approval to sell products it knows, based upon its own testing, [REDACTED] the pH range of Par's patents during their shelf-life. Par's experts were not required to opine on the ultimate conclusion of specific intent to induce infringement, which, as with willfulness and other matters of intent, is for the Court to determine. Indeed, it arguably would have been improper for them to do so, as it would involve experts purporting to divine the mind of Eagle.¹ Thus, Par's experts served expert reports discussing the technical evidence and factual matrix from which Par intends to argue inducement.

In his rebuttal report, Eagle's expert (Dr. Park) crossed the line from expert to mind reader by [REDACTED] Ex. 1, ¶¶ 161, 164. The parties provided for reply reports in this case, where Dr. Kirsch included [REDACTED] Mot. at 2, citing Mot.Ex. 3 ¶¶ 43-46, 69-70. Eagle never moved to strike his opinions and took his deposition, where they questioned him about those opinions.

Eagle's motion is based on the false predicate that an expert must provide an ultimate opinion on specific intent to support liability. That is not the law.

¹ See *AU New Haven, LLC v. YKK Corp.*, 15-cv-3411 (GHW), 2019 WL 1254763, at *13 (S.D.N.Y. Mar. 19, 2019).

Induced infringement requires proof of specific intent, *i.e.*, that “the alleged infringer’s actions induced infringing acts and that he knew or should have known his actions would induce actual infringements.” *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006). Circumstantial evidence is sufficient. *See AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010). In Hatch-Waxman cases, one can prove intent where the proposed label contains instructions that would inevitably lead some consumers to practice the claimed invention. *Id.* ANDA product specifications can also serve as evidence of intent. *See Sunovion Pharms., Inc. v. Teva Pharms. USA, Inc.*, 731 F.3d 1271, 1279 (Fed. Cir. 2013) (“If it had no intent to infringe, Reddy should not have requested, or should not accept, approval to market a product within the scope of the claim.”).

Here, Eagle was obviously aware of Par’s patents and their scope. And, Par timely served contentions and opening expert reports disclosing the predicate evidence establishing that Eagle’s actions will induce infringing acts, including:

- [REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]

Eagle does not dispute that Par timely disclosed this evidence, which sufficiently proves Eagle's intent to induce infringement.²

As to Dr. Kirsch's reply report, the complained-of opinions were proper reply to Eagle's non-infringement report. Specifically, Dr. Park offered an opinion that Eagle "does not have the intent that third-parties will infringe" based on

[REDACTED] Ex. 1,

¶¶ 161, 164. Dr. Kirsch was entitled to address those opinions consistent with his opening report, particularly that [REDACTED]

[REDACTED]

[REDACTED] Ex. 4, ¶¶ 32-38, 44-46, 68-70.

These opinions, disclosed in a reply report authorized by the scheduling order were timely. But even if they were not, Eagle failed to demonstrate the necessity of exclusion under the *Pennypack* factors. *See In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 791-92 (3d Cir. 1994). Eagle has made no showing of prejudice, let alone prejudice that has not or cannot be remedied before trial, which

² Eagle's motion reads like a summary judgment motion (not generally permitted in ANDA cases) in disguise, rather than a motion *in limine*. The issue here is not the substantive sufficiency of Par's infringement proofs, but whether Par's experts properly disclosed their opinions. They did.

is not yet scheduled in this case. The exclusion of Dr. Kirsch's testimony would be an extreme remedy reserved to sanction flagrant misconduct, not present here. *Id.*

Dated: May 11, 2020

Respectfully submitted,

FARNAN LLP

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*Attorneys for Plaintiffs Par Pharmaceutical,
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CERTIFICATION OF COMPLIANCE

The foregoing document complies with the type-volume limitation of this Court's March 2, 2020 form Scheduling Order For All Cases where Infringement is Alleged. The text of this brief, including footnotes, was prepared in Times New Roman, 14 point. According to the word processing system used to prepare it, the brief contains 747 words, excluding the case caption, signature block, table of contents and table of authorities.

/s/ Brian E. Farnan

Brian E. Farnan (Bar No. 4089)

Dated: May 11, 2020

EXHIBIT 1

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

PAR PHARMACEUTICAL, INC., PAR
STERILE PRODUCTS, LLC, and ENDO
PAR INNOVATION COMPANY, LLC,
Plaintiffs,

v.

EAGLE PHARMACEUTICALS INC.,
Defendant.

C.A. No. 18-00823-CFC

REBUTTAL EXPERT REPORT OF KINAM PARK, PH.D.

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I. INTRODUCTION

1. I have been asked by Defendant Eagle Pharmaceuticals, Inc. (“Eagle”) to provide my opinions regarding whether Eagle’s sale of its proposed generic vasopressin product described in ANDA No. 211538, together with the proposed label set forth in that ANDA, would directly infringe or induce infringement of certain claims of U.S. Patent Nos. 9,687,526 (the “’526 patent”), 9,744,209 (the “’209 patent”), and 9,750,785 (the “’785 patent”) (collectively, the “Patents-in-Suit”) that Plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC (“Plaintiffs” or Par”) have asserted in this action.

2. I have also been asked to respond to the November 15, 2019 reports of Zlatan Coralic, Pharm.D., BCPS, Lee E. Kirsch, Ph.D., and Robert Minkin, FACHE, submitted on behalf of Par in support of its infringement allegations with respect to those asserted claims. To the extent I do not address any aspects of these reports, it should not be taken as an admission that I agree with them.

3. The opinions expressed herein are based on information available to date. I expressly reserve the right to supplement or amend my opinions as additional information becomes available to me. I further reserve the right to address any matters raised by Par and any opinions provided by experts on behalf of Par, including at any hearing or at trial.

4. I submitted an expert report addressing invalidity of the Patents-in-Suit on November 15, 2019. I incorporate herein the Introduction, Qualifications, Compensation, and Prior Testimony sections of that report.

II. ASSERTED CLAIMS

5. I understand that Par is asserting that Eagle will infringe the following claims of the Patents-in-Suit:

- ’526 patent, claims 1 and 5–20

d. There is no evidence that Eagle will induce infringement

158. Even if Eagle's ANDA Product could infringe or be used to infringe the Patents-in-Suit, I am not aware of any evidence that Eagle will induce that infringement. As noted above, I understand that Par and its experts do not allege that Eagle will perform the claimed methods in the '526 and '209 patent, and therefore directly infringe those patents. And as also discussed above, there is no evidence that Eagle will make, use, sell, offer to sell, or import a composition having the properties required by the '785 patent, and therefore directly infringe that patent.

159. Par has not alleged that Eagle will induce infringement of the '785 patent, nor do its experts provide any analysis as to how it could or would. I reserve the right to respond should Par and its experts be permitted to present such contentions and opinions after the date of this Report.

160. I understand that Par does, however, allege that Eagle will induce infringement of the '526 and '209 patent method claims. I also understand that, to induce infringement, Eagle must have the knowledge and intent to induce someone else to infringe.

161. As explained in detail above, however,

[REDACTED]

[REDACTED] Thus, it does not have the intent that third parties will infringe the '526, '209 or '785 patents.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

165. Even further, with respect to the '526 patent, there is no evidence that Eagle's ANDA Product would ever reach a pH of 3.8 at least four weeks before the expiration date, as required in order to store the claimed formulation for four weeks before administration according to Eagle's Label. In this regard, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

1. A method of increasing blood pressure in a human in need thereof, the method comprising:

¹⁷ Claim 13 additionally requires less than 1% degradation after storage at 2–8°C for about four weeks.

[REDACTED]

a) *providing a pharmaceutical composition* for intravenous administration comprising: i) from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically-acceptable salt thereof; ii) acetic acid; and iii) water,

wherein the pharmaceutical composition has a pH of 3.8;

b) *storing the pharmaceutical composition at 2-8° C. for at least 4 weeks;* and

c) intravenously administering the pharmaceutical composition to the human,

wherein the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute,

wherein the human is hypotensive,

wherein the pharmaceutical composition exhibits less than about 5% degradation after storage at 2-8° C. for about four weeks.

'526 patent claim 1 (emphasis added).

166. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

167. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

168. For these reasons, it is my opinion that, even if Eagle's ANDA Product or use of Eagle's ANDA Product could infringe any of the remaining Patents-in-Suit, there is no evidence that Eagle is inducing such infringement.

200. By way of example, whether the Registration Batches had the specific impurities described in the dependent claims, and at the requisite amounts, depended on how long and at what temperature the batch was stored. [REDACTED]

[REDACTED] See EAGLEVAS0047274; EAGLEVAS0047284; EAGLEVAS0047294. [REDACTED]

201. Finally, Dr. Kirsch's reliance on Eagle's ANDA specification as possibly showing infringement of these impurity and degradation limitations is inconsistent with his other opinions.

5. There Is No Evidence That Eagle Will Induce Infringement

202. Even if Eagle's ANDA Product could infringe or be used to infringe the Patents-in-Suit, I am not aware of any evidence that Eagle will induce that infringement. As noted above, I understand that Par and its experts allege that Eagle will induce infringement of the '526 and '209 patent method claims, but that Par has not alleged that Eagle will induce infringement of the '785 patent, nor do its experts provide any analysis as to how it could or would. I also understand that, to induce infringement, Eagle must have the knowledge and intent to induce someone else to infringe.

[REDACTED]

203. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

204. For instance, with respect to the '526 patent, there is no evidence that Eagle's ANDA Product would ever reach a pH of 3.8, be stored for at least four weeks, and *then* exhibit less than 5% or 1% degradation. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Moreover, as noted above, in addition to allowing storage at different temperatures, Eagle's Label does not require storage *for at least four weeks*. That is, the storage conditions described in Eagle's Label allow Eagle's ANDA Product to be used prior to storage for at least four weeks.

205. Additionally, with respect to the '209 and '785 patents, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] And, with respect to the '209 patent, this batch would not have been "administer[ed] to [a] human."

[REDACTED]

206. For these reasons, it is my opinion that, even if Eagle's ANDA Product or use of Eagle's ANDA Product could infringe any of the remaining Patents-in-Suit, there is no evidence that Eagle is inducing such infringement.

D. The HPLC Requirements of the '209 and '785 Will Not Be Met By Eagle's ANDA Product

207. Claim 11 of the '209 patent and claim 2 of the '785 patent require that "impurities are determined based on" the specified HPLC method. As I stated in my Opening Report, I understand from Dr. Amiji's analysis that is unclear what the requirements are of the HPLC claims of the '209 and '785 patents, especially as to whether these claims require the performance of the recited method, are product-by-process limitations, or define the impurities recited in the independent claims by how they may be analyzed.

208. I understand Dr. Kirsch's analysis to conclude that Eagle infringes the claims by performance of the recited method, *i.e.*, that Eagle infringes these claims because the claimed method was used to determine impurities present in Eagle's ANDA Product. It is not clear how a composition claim can require a particular HPLC method to detect impurities. In any event, as I discuss in detail below, Eagle's HPLC method²¹ does not infringe the claimed method.

1. [REDACTED]

209. Claim 11 of the '209 patent and claim 2 of the '785 patent depend from claim 1 and, thus, the HPLC method recited in these claims is used to determine the impurities present in a vasopressin formulation having a pH of 3.7 – 3.9. [REDACTED]

[REDACTED]

[REDACTED]

²¹ As discussed above, testing of Eagle's ANDA Product was performed in conjunction with AMRI/Oso.

Dated: December 23, 2019

A handwritten signature in black ink, reading "Kinam Park", is positioned above a horizontal line. The signature is written in a cursive style with a large, looped "P".

Kinam Park, Ph.D.

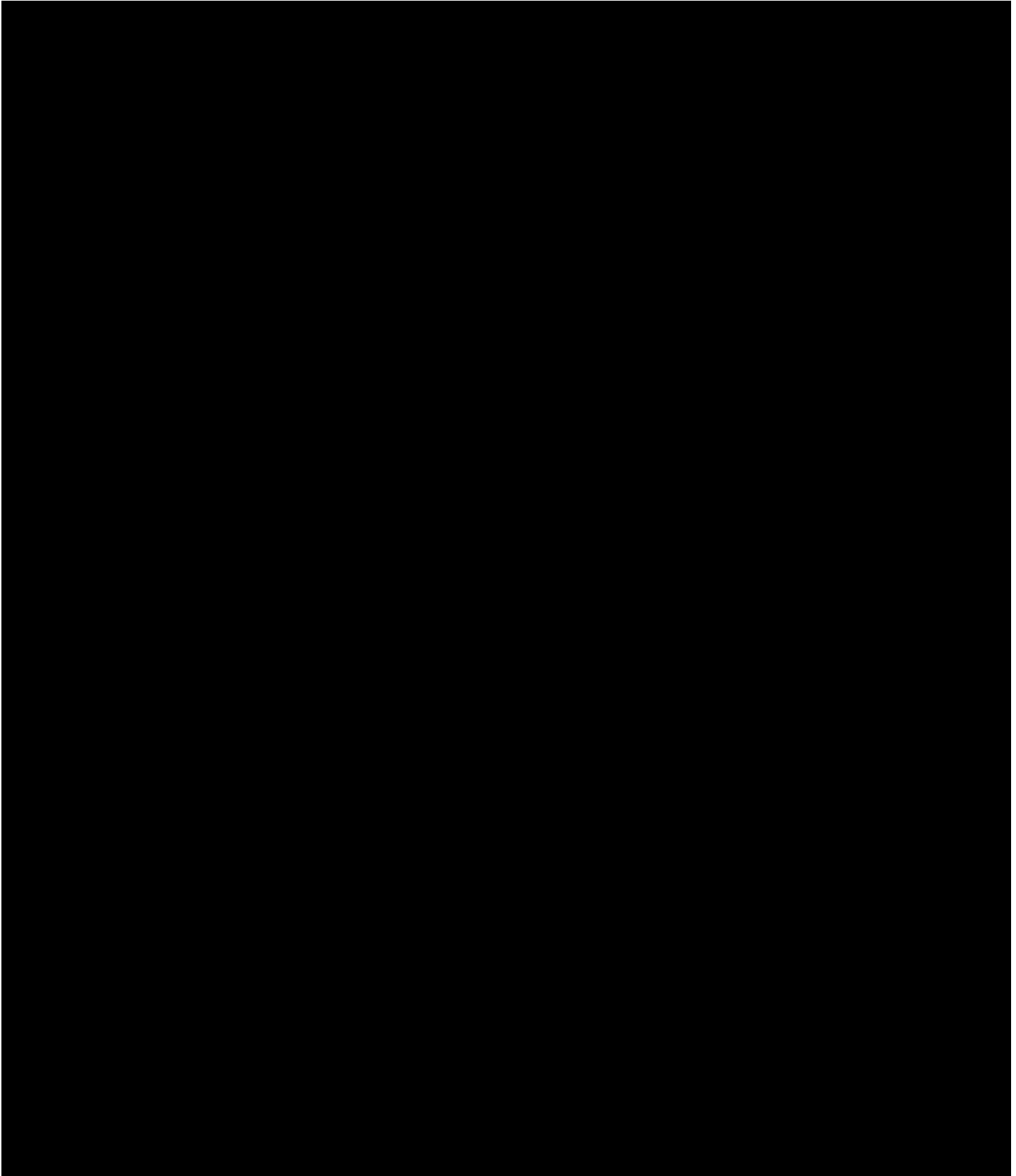
EXHIBIT 2

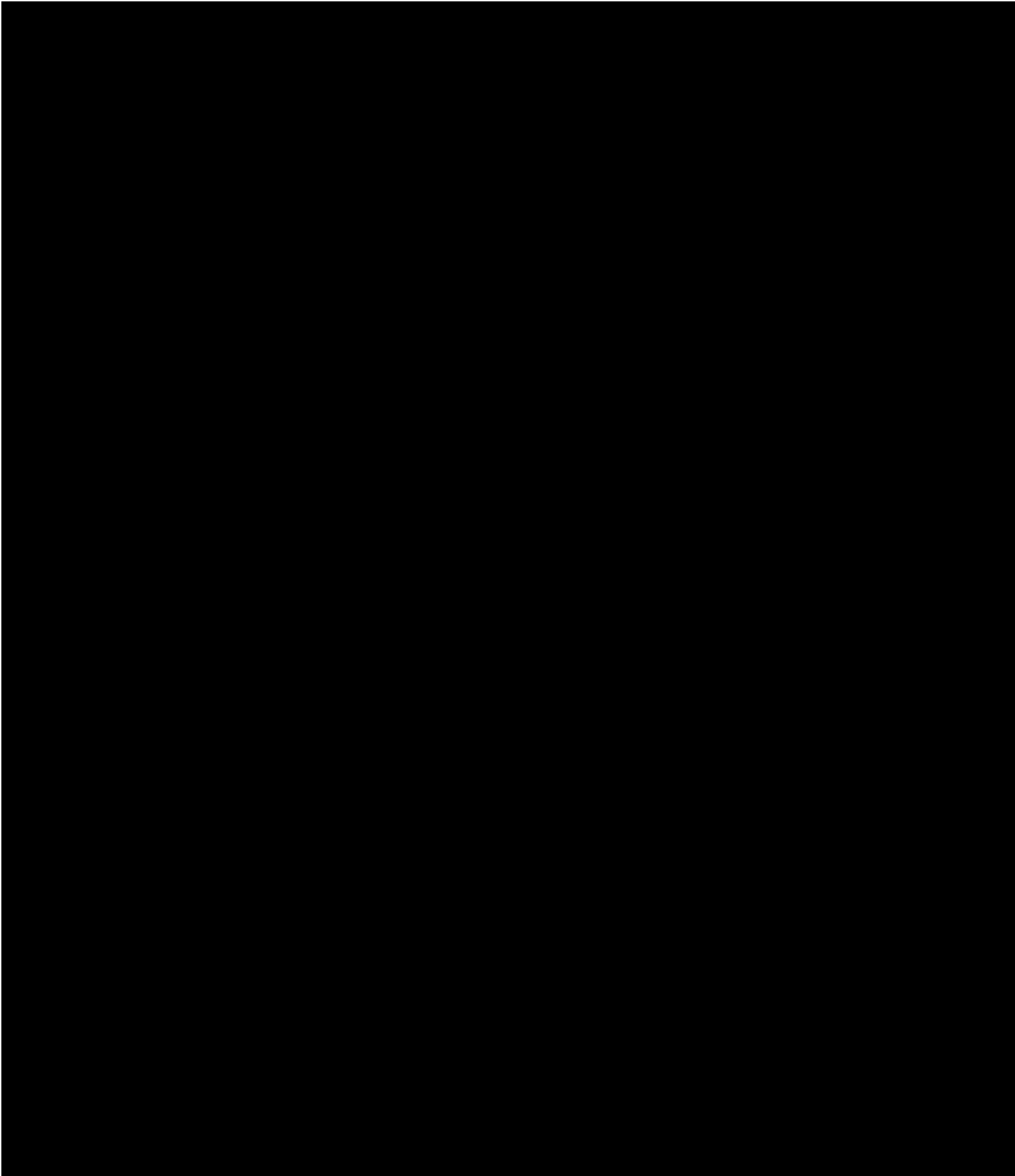
REDACTED

EXHIBIT 3

REDACTED

EXHIBIT C





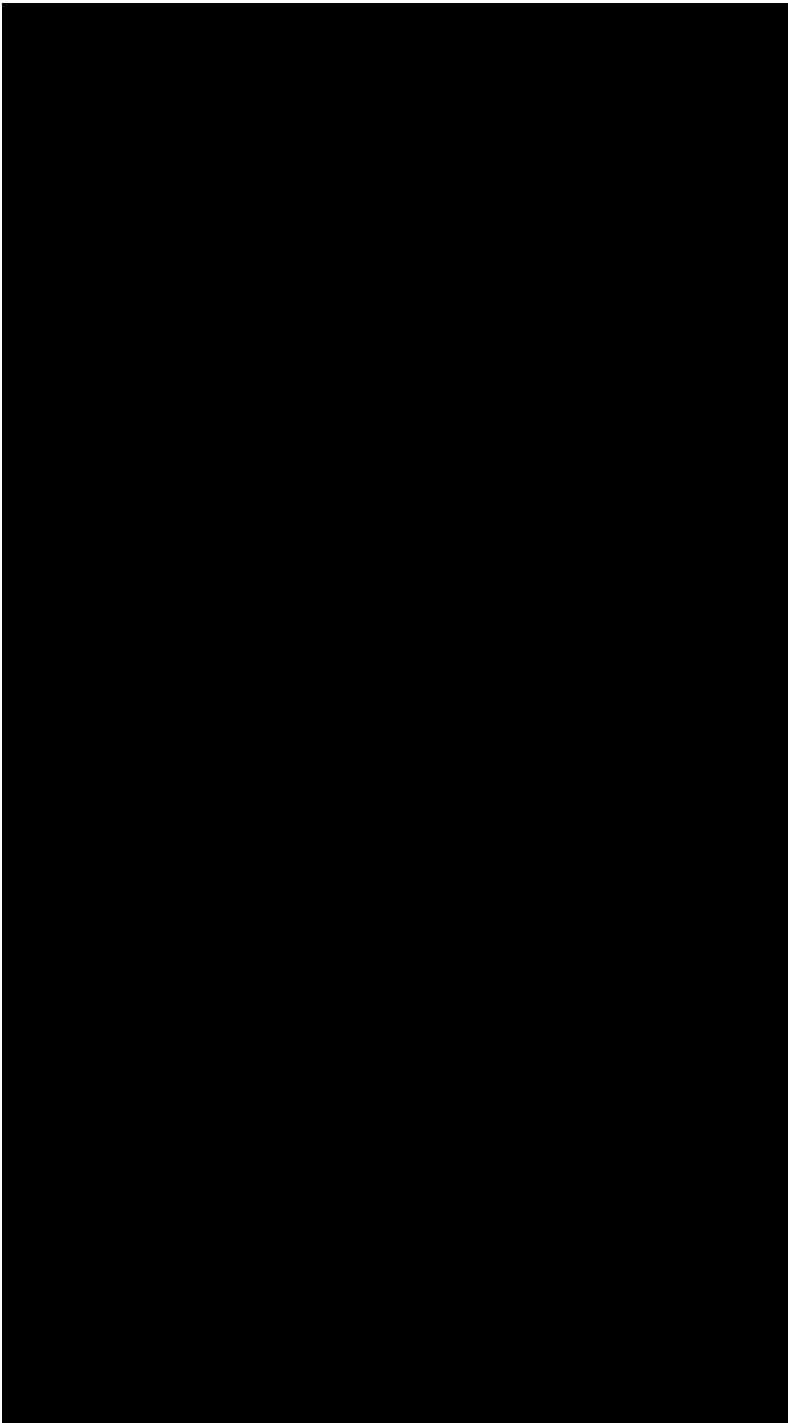


EXHIBIT D

EXHIBIT D
INFRINGEMENT CLAIM CHART FOR U.S. PATENT NO. 9,744,209

<p>1. A method of increasing blood pressure in a human in need thereof, the method comprising</p>	
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administering to the human
a unit dosage form, wherein

<p>the unit dosage form comprises from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically acceptable salt thereof, wherein:</p> <p>the unit dosage form has a pH of 3.7-3.9;</p> <p>the unit dosage form further comprises impurities that are present in an amount of 0.9% - 1.7%, wherein the impurities have from about 85% to about 100% sequence homology to SEQ ID NO.: 1;</p>	<p>These are formulation-related limitations, and as noted in the body of my report, I rely on the opinions of Plaintiffs' other expert (Dr. Kirsch) for the conclusion that Eagle's ANDA Product will satisfy these limitations for at least some portion of the Product's intended shelf life.</p> <p>I note that, as explained in the body of my report, each vial of Eagle's ANDA Product will have stamped on it the expiration date for that particular vial. [REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED] See EAGLEVAS0043670, at 43778; EAGLEVAS0013355, at 13367. The drug product can be used at any time prior to its expiration date.</p> <p>[REDACTED]</p> <p>[REDACTED]</p>
<p>the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute; and,</p>	<p>[REDACTED]</p>

the human is hypotensive.	

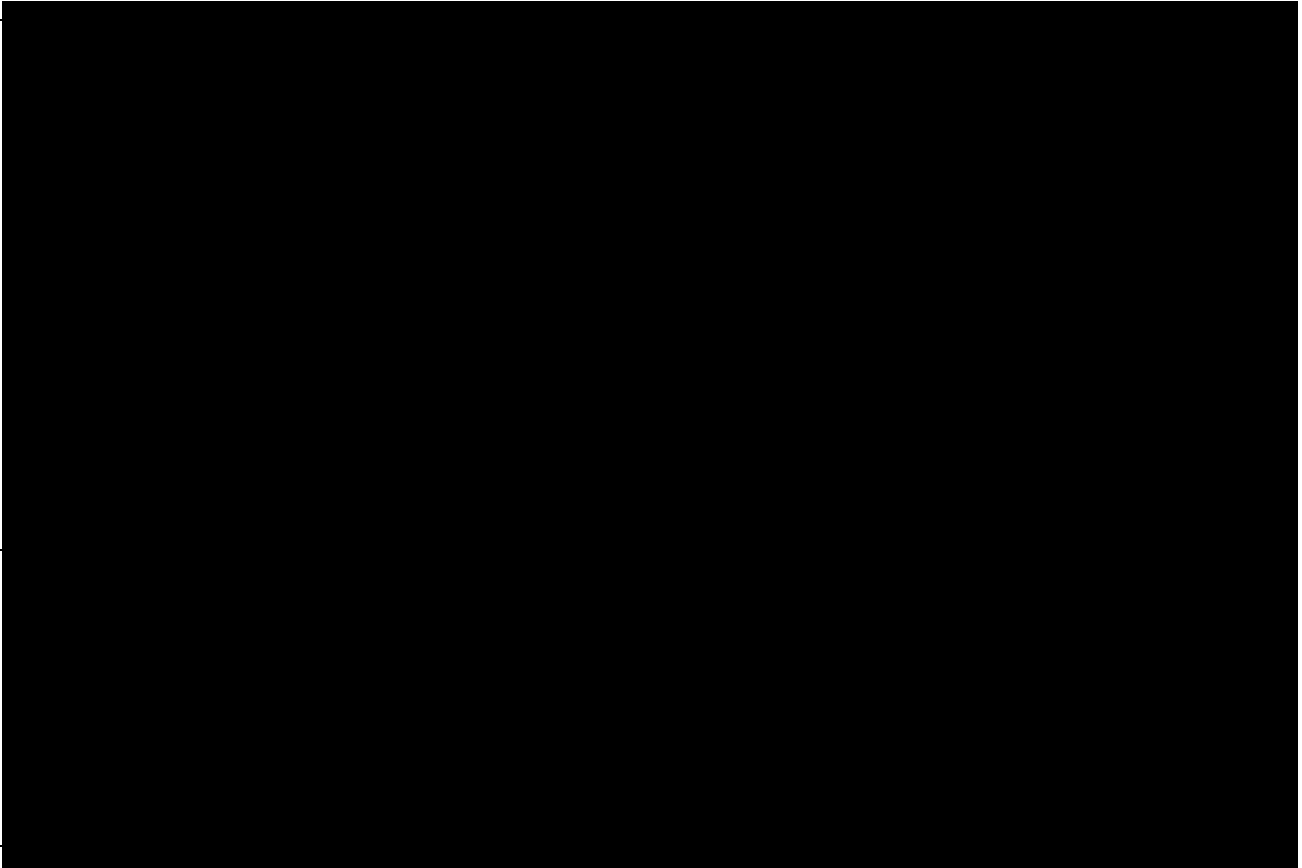
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2. The method of claim 1,	The use and administration of the Eagle ANDA Product in accordance with the instructions set forth on the proposed package insert will result in the performance of all of the steps of the method of claim 1, for the reasons set forth above.
wherein the impurities comprise SEQ ID NO.: 2, and SEQ ID NO.: 2 is present in the unit dosage form in an amount of 0.1% to 0.3%.	This is a formulation-related limitation, and as noted in the body of my report, I rely on the opinions of Plaintiffs' other expert (Dr. Kirsch) for the conclusion that Eagle's ANDA Product will satisfy the formulation-related limitations of this claim.

3. The method of claim 1,	The use and administration of the Eagle ANDA Product in accordance with the instructions set forth on the proposed package insert will result in the performance of all of the steps of the method of claim 1, for the reasons set forth above.
wherein the impurities comprise SEQ ID NO.: 3, and SEQ ID NO.: 3 is present in the unit dosage form in an amount of 0.1%.	This is a formulation-related limitation, and as noted in the body of my report, I rely on the opinions of Plaintiffs' other expert (Dr. Kirsch) for the conclusion that Eagle's ANDA Product will satisfy the formulation-related limitations of this claim..

EXHIBIT E

EXHIBIT E
INFRINGEMENT CLAIM CHART FOR U.S. PATENT NO. 9,687,526

1. A method of increasing blood pressure in a human in need thereof, the method comprising:	
a) providing a pharmaceutical composition for intravenous administration comprising:	



<p>i) from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically-acceptable salt thereof;</p> <p>ii) acetic acid; and iii) water,</p> <p>wherein the pharmaceutical composition has a pH of 3.8;</p>	<p>These are formulation-related limitations, and as noted in the body of my report, I rely on the opinions of Plaintiffs' other expert (Dr. Kirsch) for the conclusion that Eagle's ANDA Product will satisfy these limitations for at least some portion of the Product's intended shelf life.</p> <p>I note that, as explained in the body of my report, each vial of Eagle's ANDA Product will have stamped on it the expiration date for that particular vial. [REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p>
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b) storing the pharmaceutical composition at 2-8° C for at least 4 weeks; and

c) intravenously administering the pharmaceutical composition to the human,

wherein the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute,

wherein the human is hypotensive,	

	<div></div> <div></div>
wherein the pharmaceutical composition exhibits less than about 5% degradation after storage at 2-8° C for about four weeks.	This is a formulation-related limitation, and as noted in the body of my report, I rely on the opinions of Plaintiffs' other expert (Dr. Kirsch) for the conclusion that Eagle's ANDA Product will satisfy this limitation.

5. The method of claim 1,	The use and administration of the Eagle ANDA Product in accordance with the instructions set forth on the proposed package insert will result in the performance of all of the steps of the method of claim 1, for the reasons set forth above.
wherein the human's mean arterial blood pressure is increased within 15 minutes of administration.	<div></div>

EXHIBIT 4

REDACTED

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**


PAR PHARMACEUTICAL, INC.,)	
PAR STERILE PRODUCTS, LLC, and)	
ENDO PAR INNOVATION)	
COMPANY, LLC,)	
)	C.A. No. 18-823-CFC
Plaintiffs,)	
)	
v.)	
)	
EAGLE PHARMACEUTICALS INC.,)	
)	
Defendant.)	

EXHIBIT 16.2.3

**DEFENDANT'S REPLY IN SUPPORT OF MOTION *IN LIMINE* NO. 2
TO PRECLUDE TESTIMONY REGARDING
SPECIFIC INTENT TO INDUCE INFRINGEMENT**

Par's opposition confirms exclusion is warranted.

First, Par contends its experts "were not required to opine" on Eagle's intent, and "it would have been improper for them to do so." (Opp'n at 1.) In that case, there is no question Dr. Kirsch's opinions should be excluded. And providing such opinions for the first time in reply, which Par acknowledges (*id.*), is even worse. If Dr. Kirsch's intent opinion is appropriate, it should have been disclosed in his opening report.

Second, Par attempts to retroactively recreate its belated intent theory—that Eagle "knows" [REDACTED] by cobbling together disparate "facts" from contentions and multiple opening reports. (*Id.*) But Par identifies no disclosure linking the "facts" it allegedly "properly disclosed" to intent. Neither its contentions nor opening reports ever discussed intent. (Mot. at 1.) Par knew of Eagle's release specifications [REDACTED] (Opp'n at 3), yet never mentioned them in its contentions or opening reports, much less to show Eagle's intent.

Third, Par notes "Eagle never moved to strike [Dr. Kirsch's] opinions and took his deposition." (Opp'n at 1.) But the same applies to the opinions *Par* seeks to exclude. (Par's Mot. Limine No. 1.) And in contrast to Eagle's experts, Par's experts refused to explain their opinions on intent or the underlying facts Par identifies. (Mot. at 2-3; Ex. 5 at 145:11-153:5.) Thus, Eagle was unable to investigate Par's

untimely theory. Nor does Par propose how Eagle's prejudice could otherwise be cured. (Opp'n at 3-4.)

Date: May 11, 2020

POTTER ANDERSON & CORROON LLP

By: /s/ Bindu A. Palapura

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Pharmaceuticals Inc.*

CERTIFICATION OF COMPLIANCE

The foregoing document complies with the type-volume limitation of this Court's March 2, 2020 form Scheduling Order For All Cases where Infringement is Alleged. The text of this brief, including footnotes, was prepared in Times New Roman, 14 point. According to the word processing system used to prepare it, the brief contains 250 words, excluding the case caption, signature block, table of contents and table of authorities.

Date: May 11, 2020

/s/ Bindu A. Palapura
Bindu A. Palapura (Bar No. 5370)

EXHIBIT 5

REDACTED